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U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21, No. 1
January 10, 1992

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National Institutes of Health

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NOTICES

USE OF THE STATEMENT OF APPOINTMENT FORM (PHS 2271) FOR INDIVIDUALS APPOINTED TO MINORITY SUPPLEMENT AWARDS AND PROGRAM CAREER AWARDS

P.T. 44; K.W. 1014006

National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration

Beginning in Fiscal Year 1992, a "Statement of Appointment" form (PHS 2271, revision 9/91) must be completed and sent to the PHS Awarding Component whenever an individual is appointed to one of the following programs:

- o Any NIH Career Development Program Award (K12 or K16)
- o Any Research Supplement for Underrepresented Minorities

The form MUST be completed and submitted to the PHS at the time an individual STARTS an appointment, a reappointment, or when the name or permanent mailing address of the appointed individual changes. A reappointment includes the extension of an appointment into a new budget period. The form must be signed by both the appointed individual and the Principal Investigator of the Career Development Program Award or the supplemented research grant.

The Statement of Appointment form will continue to be required for all appointments to National Research Service Award Institutional Research Training Grants (T32, T34). This requirement does not apply to individual NIH career awards (K04, K07, K08, K11, K14, K15, K16; ADAMHA - K20, K21).

The Statement of Appointment form has been substantially revised, and the new form dated Rev. 9/91 must replace all previous versions. Only the revised form will be accepted after May 10, 1992.

The form dated Rev. 9/91 is available from the Office of Administrative Services, Division of Research Grants, National Institutes of Health, Westwood Building, Room 436, Bethesda, MD 20892, telephone 301-496-9797.

INQUIRIES

Inquiries may be directed to:

Dr. Walter T. Schaffer
Director, Research Training and Special Programs Office
Office of Extramural Programs
National Institutes of Health
Building 31, Room 5B44
Bethesda, MD 20892
Telephone: (301) 496-9743

NOTICE OF REGIONAL MEETINGS

P.T. 42; K.W. 1014006, 1014002

National Institutes of Health

The National Institutes of Health (NIH) has been engaged in a strategic planning process aimed at developing the Agency's first corporate long-range Strategic Plan. The purpose of the NIH Strategic Plan is to: (1) identify areas of research that promise extraordinary dividends for the Nation's future health, (2) nurture the intellectual base of biomedical research and the conditions that lead to breakthroughs on the cutting edge of science, and (3) provide approaches for addressing broad administrative and science policy issues that affect the ability of the NIH to carry out its mandate. The Strategic Plan incorporates the ideas of all the organizational components of the NIH as well as the research components of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA).

The NIH will convene two regional meetings to provide a forum for the extramural community to comment on the draft Strategic Plan before it is finalized. The first meeting will take place on February 12, 1992, at Occidental College, Los Angeles, California, and will be co-hosted by Occidental College and the Charles R. Drew University of Medicine and Science. The second meeting will be held on February 25, at the University of Connecticut Health Center, Farmington, Connecticut.

Each of the regional meetings will be of one day duration, beginning at 9 a.m. and ending at 3 p.m. The meetings will begin with the NIH Director presenting an overview of the NIH Strategic Plan. Immediately afterwards, representatives of concerned organizations and institutions will be invited to present testimony before a panel of senior NIH officials, to be chaired by the Director, NIH. Due to time constraints, it would be appreciated if only one representative from each organization would present testimony; oral presentations will be limited to five minutes. Written testimony may be any length and should include a brief description of the organization presenting. Testimony will be scheduled based upon when notification of intent to present testimony is received. If the number of organizations that want to present oral testimony exceeds the time available on the agenda, the individual written statements will serve as testimony presented. All testimony, whether oral or written, will form a part of the official record of the NIH Strategic Plan.

If you or others from your organization who plan to attend one of these regional meetings have any special needs that require assistance, please inform the office listed below. If you have questions concerning either of the two regional meetings, please contact Ms. Mary Demory (301) 496-1454.

If you will be attending one of the regional meetings or if your organization would like to testify before the NIH panel, please provide the name, title, institution, telephone number, and mailing address of the individual attending. Indicate which regional meeting and whether or not testimony will be presented. The requested information is to be sent by mail or facsimile no later than December 16, 1991 to:

NIH Strategic Plan Regional Meetings
c/o Dr. Jay Moskowitz
NIH, Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892
FAX: (301) 402-1759

A copy of the Draft NIH Strategic Plan and additional information will be sent prior to the regional meetings to participants attending and/or testifying.

NATIONAL WORKSHOPS ON THE PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0783005

National Institutes of Health
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are sponsoring a series of workshops on the responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

WEST COAST WORKSHOP

DATES: January 23 and 24, 1992 (REVISED DATES)

WORKSHOP SITE: Los Angeles, CA

SPONSORS:

University of Southern California
Los Angeles, CA 90089-4014

California State University - Los Angeles
5151 State University Drive
Los Angeles, CA 90032-8202

REGISTRATION CONTACT:

Ms. Lily Patterson
Assistant to the Director
Research and Sponsored Programs
California State University - Los Angeles
5151 State University Drive
Los Angeles, CA 90032-8202
Telephone: (213) 343-3820

TOPIC: Whose Research is it Anyway? A Workshop on the Protection of Human Subjects in Research

SOUTH MIDWESTERN WORKSHOP

DATES: February 20 and 21, 1992

WORKSHOP SITE: San Antonio, TX

SPONSORS:

University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, TX 78284-7972

St. Mary's University
One Camino Santa Maria
San Antonio, TX 78228-8572

REGISTRATION CONTACT:

Ms. Angie Khan
Institutional Coordinator of Research Review

University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive (Room 402L)
San Antonio, TX 78284-7972
Telephone: (512) 567-2351

TOPIC: Identifying and Assessing Risks in Human Subject Research

SOUTHWEST WORKSHOP

DATES: March 24, 25, and 26, 1992

WORKSHOP SITE: Sheraton Old Town Hotel
800 Rio Grande Blvd., N.W.
Albuquerque, NM 87104

SPONSORS: University of New Mexico
Albuquerque, NM 87131-5126

Navajo Community College
Shiprock, NM 87420

REGISTRATION CONTACT:

University of New Mexico
Office of Continuing Medical Education
Health Sciences and Services Building (Room 140)
Box 713
Albuquerque, NM 87131-5126
Telephone: (505) 277-3942

TOPIC: Ethics, Justice, and Tribal Participation in Research with American Indians

NOTE: In conjunction with this Workshop, a session entitled, "Basic Training for IRB Members," will be held from 1:00 p.m. on March 24 until noon on March 25. During this session the Workshop participants will be divided into four IRBs that will review four different research protocols involving American Indians. The full conference will convene at 1:00 p.m. on March 25 and continue until 6:00 p.m. on March 26.

NORTHEASTERN WORKSHOP

DATES: April 27 and 28, 1992

WORKSHOP SITE: Philadelphia, PA

SPONSORS:

University of Pennsylvania
133 South 36th Street, Suite 300
Philadelphia, PA 19104-3246

Lincoln University
Lincoln University, PA 19352

REGISTRATION CONTACT:

Ms. Lynn Bevan
Assistant Director
Office of Research Administration
University of Pennsylvania
133 South 36th Street, Suite 300
Philadelphia, PA 19104-3246
Telephone: (215) 898-2614

TOPIC: The Shifting Ground: Current Issues for the Protection of Human Subjects on Biomedical and Behavioral Research

For further information regarding these workshops and future NIH/FDA National Protection of Human Subjects Workshops, please contact:

Ms. Darlene Marie Ross
Executive Assistant for Education
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
9000 Rockville Pike
Building 31, Room 5B59
Bethesda, MD 20892
Telephone: (301) 496-8101

CONFERENCE: "AGING--THE QUALITY OF LIFE"

P.T. 42; K.W. 0710010, 0745035

National Institutes of Health

The Christopher Columbus Medical Sciences Committee of the National Institutes of Health, in conjunction with several NIH institutes, the Food and Drug Administration, and the Italian National Research Council, has organized a major international conference that will be held at the Omni Shoreham Hotel in Washington, DC, February 10-12, 1992. The conference is part of the commemoration of the Quincentenary of Christopher Columbus' epic voyage to the Americas.

A banquet will be held in the evening of February 11. Presentation of the prestigious Christopher Columbus Discovery Awards to outstanding scientists in biomedical research will be the highlight of the banquet.

Topics and speakers at the Plenary Session on Monday, February 10, will be:

- o Searching for the Fountain of Youth: 500 Years of Research to Understand Aging; Dr. Robert N. Butler, Mt. Sinai Medical Center, New York;
- o Age Associated Changes in Cardiovascular Function in Response to Exercise; Dr. Myron Weisfeldt, Columbia University, New York;
- o Nutrition, Aging and Disease: The Metabolic Crossroads; Dr. Edwin L. Bierman, University of Washington;
- o Drug Metabolism/Pharmacology in the Aging; Dr. Grant R. Wilkenson, Vanderbilt University;
- o The Brain: Lighthouse of the Aging Years; Dr. Fred Plum, Cornell Medical Center;
- o Osteoporosis, Osteoarthritis, and Other Musculoskeletal Disorders in the Elderly; Dr. Lawrence E. Shulman, National Institutes of Health;
- o The Effect of Chronological Age on Cancer Biology and Therapy; Dr. Emil J. Freireich, M.D. Anderson Hospital;
- o Implications of Aging for the Individual and Society; Dr. Robert H. Binstock, Case Western Reserve; and
- o Medicare: What is Covered?/What is not Covered?; Dr. Gail Wilensky, Administrator, Health Care Financing Administration.

Concurrent sessions dealing with cardiovascular, brain, cancer, musculoskeletal, healthy aging, nutrition, obesity and urogenital research, featuring outstanding biomedical scientists, will be held on the second and third days. An interdisciplinary poster session will be held on Tuesday, February 11. Summary reports and future challenges will be presented at the final plenary session to close the conference on the third day.

The conference will be of interest to scientists, public health officials, policy makers and analysts, and the general public.

Continuing Medical Education credits for 21.5 hours in Category 1 of the Physician's Recognition Award of the American Medical Association are available.

Registration for the three-day conference is \$200 if paid in advance or \$250 on site. Early registration of \$150 has been extended to December 15, 1991. Those interested in program and registration information should contact:

Aging: Quality of Life Conference
Suzanne Kuntz, Conference Coordinator
655 Fifteenth St., N.W., Suite 300
Washington, DC 20005
Telephone: (202) 639-4524
FAX: (202) 347-6109

CONFERENCE: CARDIOVASCULAR BIOMATERIALS, DEVICES, AND BIOCOMPATIBILITY

P.T. 42; K.W. 0750005, 0715040, 0706040

National Heart, Lung, and Blood Institute

This conference is being sponsored by the National Heart, Lung, and Blood Institute (NHLBI) to be held on February 22, 1992, at the Hyatt Regency, Bethesda, MD.

PURPOSE

1. To present state-of-the-art reviews on cardiovascular biomaterials, devices, and biocompatibility for basic and clinical investigators in the field of biomaterials and biocompatibility and for persons in the device manufacturing industry and regulatory agencies.

2. To preview the contents of the revision of the widely used, NHLBI-sponsored book, "Guidelines for Blood-Material Interactions." This book was first published in 1980 and revised in 1985. The new edition is due to be published in 1993.

PROGRAM

The speakers at this meeting are chapter authors of the new edition of "Guidelines for Blood-Material Interactions." The meeting is being coordinated by Paul Didisheim, M.D., Head, Biomaterials Program, Devices and Technology Branch, NHLBI, Bethesda, MD, and will be co-chaired by Laurence Harker, M.D., Director, Division of Hematology-Oncology, Emory University School of Medicine, Atlanta, Georgia, and Buddy Ratner, Ph.D., Director, National ESCA and Surface Analysis Center for Biomedical Problems, University of Washington, Seattle, Washington.

Vincent Turitto	Fluid Mechanics and Hemorheology
Edward Leonard	Principles of Cardiovascular Device Design
Robert Colman	Mechanisms of Device-Related Thrombosis and Hemostatic Failure
James Anderson	Mechanisms of Inflammation and Infection With Implanted Devices
Peter Libby	Role of Growth Factors in Device-Related Vascular Lesion Formation
Buddy Ratner	New Techniques for Surface Analysis of Biomaterials
Jeffrey Hubbell	Basis for Selecting Materials
Stuart Cooper	Bulk Characterization of Materials
Arthur Coury	Preparation of Specimens for Blood Compatibility Testing
Ken Stokes	Biodegradation
Jeffrey Hubbell	Pharmacologic Modification of Surfaces
Sharon Northup	Cytotoxicity and Mutagenicity Testing
Dan Daniels	Mechanical Performance Testing Following Use
Thomas Horbett	Protein Adsorption
Deane Mosher	Protein-Cell-Surface Interactions
Stephen Hanson	Device Thrombosis and Thromboembolism
Don Giddens	Mechanisms of Heart Valve Failure
Alexander Clowes	Mechanisms of Vascular Graft Failure
Raymond Hakim	Systemic Effects of Extracorporeal Membrane Devices
James Anderson	Device Retrieval and Evaluation
Frederick Schoen	Approaches to Therapy and Future Directions
John Watson	Importance of Biomaterials and Biocompatibility to the Mission of NHLBI

For further information regarding the conference on "Cardiovascular Biomaterials, Devices, and Biocompatibility," contact Marla Hollander, telephone (301) 468-6555.

CME credits: The Foundation for Advanced Education in the Sciences/National Institutes of Health is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

A separate meeting, "Research Initiatives in Vascular Diseases," co-sponsored by the NHLBI, the Society for Vascular Surgery, and the International Society for Cardiovascular Surgery, will be held at the Hyatt Regency Hotel in Bethesda on February 20-21, 1992. The theme of the meeting is "Molecular Biology and Vascular Surgery."

INQUIRIES

For further information, contact Darlene Janis, telephone (508) 526-8330, fax (508) 526-4018.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

PREPARATION AND DELIVERY OF HOMOGENEOUS CERAMIDETRIHEXOSIDASE

RFP AVAILABLE: NIH-NINDS-92-03

P.T. 34; K.W. 0780005, 0760080, 0760013

National Institute of Neurological Disorders and Stroke

The National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health, has a requirement to develop a method of producing ceramidetrihexosidase by recombinant means, isolating the enzyme, and supplying it in a form suitable for intravenous injection into patients with Fabry's disease. The enzyme preparation shall consist of a single (homogeneous) protein. The purified enzyme shall catalyze the hydrolysis of a minimum of $2.0 \times 1,000,000$ nanomoles of 4-methylumbelliferyl-alpha-D-galactopyranoside per milligram of protein per hour at 37 degrees. The enzyme shall also catalyze the hydrolytic cleavage of 800,000 nanomoles of the terminal molecule of galactose from ceramidetrihexoside per milligram of protein per hour. At the time of proposal submission, the offeror's facilities must meet Food and Drug Administration standards in accordance with the Current Good Manufacturing Practices. Non-compliance with the above requirement shall immediately render the proposal technically unacceptable without the consideration of other evaluation criteria. It is anticipated that one award will be made in July 1991 for a period of three years.

This is not a Request for Proposals (RFP). To receive a copy of the RFP, submit a written request to the following address, and supply this office with two self-addressed mailing labels. All responsible sources shall be considered by the agency. The RFP will be issued on or about January 2, 1992, with proposals due on March 2, 1992.

Contracting Officer
Contracts Management Branch, DEA
National Institute of Neurological Disorders and Stroke
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892

Attention: RFP No. NIH-NINDS-92-03

ALZHEIMER'S DISEASE CENTER COMMUNITY OUTREACH EDUCATION PROGRAMS

RFA AVAILABLE: AG-92-01

P.T. 04; K.W. 0403004, 0715180, 0502017, 0745020

National Institute on Aging

Letter of Intent Receipt Date: February 21, 1992

Application Receipt Date: March 24, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The purpose of this RFA is to invite grant applications for the support of community outreach education programs from recipients of National Institute on Aging (NIA) Alzheimer's Disease Research Centers (P50) and Alzheimer's Disease Center Core Grants (P30) and institutions that have equivalent programs. It is anticipated that these education programs will result in increased community efforts related to Alzheimer's disease, to earlier detection of dementing disorders, to better education and assistance programs for the families, and to the systematic application of the best available methods for treatment and care of Alzheimer's disease patients. Underserved, women, and minority populations should receive high priority in carrying out these objectives.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Alzheimer's Disease Center Community Outreach Education Programs, is related to the priority area of health promotion: educational and community-based Programs. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Research grant applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Support of this program will be through the National Institute on Aging Education Projects Grant (R25). The total project period for applications submitted in response to this RFA may not exceed three years. The earliest start date will be September 30, 1992.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary NIH peer review procedures.

FUNDS AVAILABLE

The NIA will commit up to \$500,000 per year for three years to fund applications that are submitted in response to this RFA. It is anticipated that up to five awards will be made. Awards will be limited to a maximum of \$100,000 per year in direct costs plus eight percent indirect costs.

This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NIA, awards pursuant to this RFA are also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The purpose of this RFA is to provide funding, on a competitive basis, for the development and implementation of Alzheimer's disease education programs for Alzheimer's Disease Centers that have been awarded a P30 or P50 grant by the National Institute on Aging and institutions that have equivalent programs. These education programs must provide state-of-the-art knowledge related to the detection, diagnosis, treatment, management, and family care of the dementia patient to local and regional health care professionals, community leaders, and staff of relevant community organizations. Topics should be selected on the basis of their relevance to the day-to-day activities and problems of the community health care professionals and to the welfare of Alzheimer's disease patients and their families.

These outreach programs are intended to be of particular benefit to underserved communities and to areas with disproportionately large populations of older people. High priority local and regional needs for specific types of Alzheimer's disease education programs should be addressed by the proposed programs and described in the application.

SPECIAL REQUIREMENTS

The application must describe examples of specific topics and approaches that might be included in the Alzheimer's disease education programs. Emphasis should be given to outreach education topics that would have the greatest impact upon improving the diagnosis, treatment and management of Alzheimer's disease and on improving the quality of life of the Alzheimer's disease patient and his/her family.

An area of special interest to the NIA is educational programs designed to improve the quality of diagnosis, treatment, and management in women and ethnic, minority, low socioeconomic, and other underserved populations in the U.S.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit by February 21, 1992, a letter of intent that includes a descriptive title of the proposed project, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is requested in order to provide an indication of the number and scope of the applications to be reviewed.

The letter of intent is to be sent to:

Dr. Teresa Sluss Radebaugh
Chief, Dementias of Aging Branch
Neuroscience and Neuropsychology of Aging Program
National Institute on Aging
Gateway Building, Suite 3C307
Bethesda, MD 20892
Telephone: (301) 496-9350
FAX: (301) 496-1494

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 10/88, reprinted 9/89) must be used in applying for these grants. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892; telephone 301-496-7441; and from the NIH program administrator named below.

Applications must be received by March 24, 1992. If an application is received after that date, it will be returned to the applicant.

Detailed instructions on application submission are described in the RFA.

REVIEW CONSIDERATIONS

Applications that are not responsive to the goals and scope of this RFA will be returned to the investigator. Applications may be triaged by an NIA peer review group on the basis of relative competitiveness. Acceptable applications received in response to this RFA will be reviewed for scientific and technical merit by an appropriate peer review group convened by the National Institute on Aging. The second level of review will be provided by the National Advisory Council on Aging.

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Dr. Teresa Sluss Radebaugh
Chief, Dementias of Aging Branch
Neuroscience and Neuropsychology of Aging Program
National Institute on Aging
Gateway Building, Suite 3C307
Bethesda, MD 20892
Telephone: (301) 496-9350
FAX: (301) 496-1494

Direct inquiries regarding fiscal matters to:

Mr. Joseph Ellis
Grants Management Office
National Institute on Aging
Gateway Building, Suite 2N212
Bethesda, MD 20892
Telephone: (301) 496-1472

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.866. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

LONG-TERM CARE AND MINORITY AGING

RFA AVAILABLE: AG/NR-92-02

P.T. 34, FF; K.W. 0730000, 0710010, 0408006

National Institute on Aging
National Center for Nursing Research

Letter of Intent Receipt Date: February 4, 1992

Application Receipt Date: March 19, 1992

PURPOSE

The National Institute on Aging (NIA) and the National Center for Nursing Research (NCNR) announce the availability of a Request for Applications (RFA) for research on formal and informal long-term care patterns, determinants of such patterns, and emergent long-term care needs among African American, Asian, Pacific Islander, Hispanic, and Native American older people. Available national data show overall proportionally lower use of many formal long-term care services among minorities compared to the overall population. Use of other health and aging services, actual living arrangements of frail minority elders, and informal care networks of older minority individuals are poorly documented. Knowledge of, or data on, long-term care preferences among minority groups and subpopulations are similarly neglected. Other reasons that may contribute to ethnic and racial differences in long-term care patterns are attitudes, economic barriers, language, or institutional characteristics that are insensitive to minorities. Studies of minority long-term care have immediate practical and policy implications as well as importance for long-range planning.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Long-Term Care and Minority Aging, is related to the priority area of older adults, specifically, key services and protection objectives targeting older adults, and to the priority area of special populations. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Health People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications for research grants may be made by public or private, for-profit or non-profit organizations such as universities, colleges, hospitals, or laboratories. Minority and women investigators in particular are encouraged to apply. Where appropriate, applicants must demonstrate access to and ability to work with the selected minority research populations. Applications from or collaboration with minority institutions and organizations are also encouraged. Foreign institutions are eligible to apply but are advised to consult NIA

or NCNR staff, are encouraged to apply in association with a U.S. institution, and the research must deal with a U.S. minority population.

MECHANISM OF SUPPORT

This RFA will use the National Institute of Health (NIH) traditional research project grant (R01) mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement.

FUNDS AVAILABLE

It is estimated that up to \$2.05 million will be committed to fund the first-year total costs of up to nine grants in response to this RFA. Costs of each grant may vary according to research designs. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit and the availability of funds. The total project period for applications submitted in response to this RFA may not exceed four years. The anticipated award date will be September 30, 1992. This RFA is a one-time solicitation. Extensions may be proposed only through application as a competing continuation project.

RESEARCH OBJECTIVES

- o Identify and understand current patterns of informal care and use of formal aging services among minority older people that differ from other populations.
- o Examine determinants (e.g., culturally related attitudes, cultural preferences, economic barriers, institutional characteristics) that account for patterns of use and access to formal and informal care services among minority older people.
- o Determine the consequences of variations in long-term care for the well being of minority older people (e.g., health status, continued community involvement), their families (e.g., quality of family relationships in multigeneration households, decisions about formal care), and for service delivery (e.g., institutional admission and placement policies, impact of special programs to reach minorities).

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN IN CLINICAL RESEARCH STUDY POPULATIONS

Because of the nature of this RFA, minority populations are to be included in each application. The minority or other population(s) must be carefully delineated. NIH requires applicants to give special attention to the inclusion of women in study population. If women are not included in the study populations, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

The RFA, which contains important information for applicants, may be requested from Dr. Katrina Johnson at the address below. Applicants must use the research project application form (PHS 398, revised 10/88, reprinted 9/89) that is available at the applicant's institutional research office and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892, telephone 301-496-7441).

Applications must be received by March 19, 1992.

LETTER OF INTENT

Prospective applicants are asked to submit, by February 4, 1992, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application is being submitted. The letter of intent is to be sent to Dr. Katrina Johnson at the address below.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows Institute staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

REVIEW PROCEDURES

A complete description of the review procedures and criteria is provided in the RFA.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify issues or questions from potential applicants is welcome.

Requests for the RFA and inquiries and the letter of intent are to be sent to:

Katrina W. Johnson, Ph.D.
National Institute on Aging
Gateway Building, Room 2C-234
7201 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-3136

or to:

Patricia Moritz, R.N., Ph.D.
National Center for Nursing Research
Building 31, Room 5B-03
Bethesda, MD 20892
Telephone: (301) 496-0523

Direct inquiries regarding fiscal matters to:

Ms. Linda Whipp
National Institute on Aging
Gateway Building, Room 2N-212
7201 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-1472

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.866. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 79- 410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements Executive Order 12372 or Health Systems Agency review.

COOPERATIVE CONTRACEPTIVE DEVELOPMENT RESEARCH CENTERS PROGRAM

RFA AVAILABLE: HD-92-06

P.T. 04; K.W. 0750020, 1003006, 1003012, 0413002, 0710100, 0710030

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: January 31, 1992

Application Receipt Date: April 24, 1992

OVERVIEW

The National Institute of Child Health and Human Development (NICHD) announces the availability of a Request for Applications (RFA) for cooperative agreements from investigators willing to participate with the NICHD in establishing a Centers program designed to conduct comprehensive research to develop new methods to regulate fertility. The aim of this Center will be to conduct a wide range of research activities that, with time, will result in clinically useful products. The scope of the proposed program should involve the concurrent development of at least three projects. Each project comprises activities related to the development of a specific method for fertility regulation. Thus, research dealing with the development of a compound for male fertility regulation would be classified as a single project. Investigators are invited to propose development of methods, other than abortion related, that can serve the needs of the American public.

It is the intent of the NICHD to establish a total of three Contraceptive Development Research Centers. Two Centers were funded under a prior RFA and one Center will be funded as a result of the present RFA. Grantee institutions in the United States that meet the requirements are eligible to participate.

MECHANISM OF SUPPORT

The funding mechanism to be used to assist the scientific community in establishing this Center will be the U54 Specialized Center cooperative agreement between the participating Center and NICHD. The major difference between a cooperative agreement and a research grant is that there will be substantial programmatic involvement of NICHD staff above and beyond the levels required for traditional program management of grants. It is expected one application will be funded for a five-year period, contingent upon the receipt of a sufficient number of meritorious proposals, within the total cost limit of \$750,000 available for the first year of this award.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Cooperative Contraceptive Development Research Centers Program, is related to the priority area of family planning.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

REVIEW PROCEDURES

A preliminary review will be done by NICHD staff upon receipt of the applications. Any application that does not meet the minimal requirements of this RFA will be judged to be unresponsive to this RFA and will be returned to the applicant without technical review. Applications that are complete and responsive may be subjected to a triage procedure by peer review to determine competitiveness among the applications. Applications judged to be competitive for awards will be reviewed in detail in accordance with established NIH peer review procedures for research grants. Project site visits are neither planned nor a prerequisite of the review procedure. The review will be conducted for scientific and technical merit by a special review committee convened specifically for this purpose by the Division of Scientific Review, NICHD. This will be followed by a second-level review by the National Advisory Child Health and Human Development (NACHHD) Council in September 1992.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included or adequately represented in the study populations for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the names of the Principal and Co-Investigators, identify the cooperating institutions, and indicate whether the application will be for a Field Center, Coordinating Center, or both. The NICHD requests such letters only for the purpose of providing an indication of the number and scope of applications to be received and, usually does not acknowledge their receipt. A letter of intent is not binding, it will not enter into the review of any application subsequently submitted, nor is it a necessary requirement for applications. This letter of intent is to be received no later than January 31, 1992, and is to be sent to Dr. Gabriel Bialy at the address listed below.

Applications must be submitted on form PHS 398 (revised 10/88, reprinted 9/89), which is available in most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, NIH, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441.

INQUIRIES

Direct requests for the RFA and inquiries on programmatic issues to:

Gabriel Bialy, Ph.D.
Contraceptive Development Branch
National Institute of Child Health and Human Development
Executive Plaza North, Room 600
Bethesda, MD 20892
Telephone: (301) 496-1661

Direct inquiries regarding fiscal matters to:

Ms. Melinda Nelson
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 505
Bethesda, MD 20892
Telephone: (301) 496-5481

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93,864, Population Research. Awards will be made under the authority of the Public Health Service Act 301 (42 USC 241) and 441 (USC 289d) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NCI/MARC SUMMER TRAINING SUPPLEMENT

PA: PA-92-26

P.T. 44, FF; K.W. 0720005, 0715035

National Cancer Institute

Application Receipt Date: February 1, 1992

PURPOSE

The Comprehensive Minority Biomedical Program (CMBP) of the Division of Extramural Activities (DEA), National Cancer Institute (NCI), invites interested grantee institutions that have Minority Access to Research Careers (MARC) grants to apply for CMBP support of MARC scholars interested in obtaining laboratory research experience at the NCI. This program announcement shall be re-issued on an annual basis.

The NCI, through a co-funding arrangement with the MARC program of the National Institute of General Medical Sciences (NIGMS), provides support for research training to minority individuals and institutions and conference grant support to further address and enhance the mission of the National Cancer Program. The NCI/MARC Summer Training Program is an extension of the co-funding process.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Health People 2000," a PHS-led national activity for setting priority areas. This program announcement, NCI/MARC Summer Training Supplement, is related to the priority area of cancer research. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY CRITERIA

All domestic institutions with active MARC research training grants are eligible to apply.

MECHANISM OF SUPPORT

A MARC honors training grant (T34) to the academic institution requesting support for a student will be administratively supplemented. Unless otherwise noted, all PHS and NIH grants policies apply to applications received in response to this announcement.

The supplement will provide the following: (1) A subsistence of \$300 per week (\$3,000 for a maximum ten-week period), and (2) round-trip transportation (from MARC student's academic institution to the National Institutes of Health, Bethesda, Maryland, and return to student's academic institution). Indirect costs may be awarded to the institution for up to a maximum of eight percent of the direct costs.

RESEARCH OBJECTIVES

The purpose of this award is to increase research training opportunities in the NCI for underrepresented minority scholars and to increase the number of minority scholars entering cancer-related research careers through the influence of short-term laboratory training at the NCI.

REVIEW PROCEDURES

Applications in response to this announcement will be considered by NCI Staff; final selection for laboratory experience will be made by the relevant laboratory directors. Selection will be made on the following criteria:

- o The strength of the interest in pursuing a laboratory experience in the biomedical sciences based on the statement from the student;
- o The strength of the letters of recommendation;
- o Cumulative grade point average (2.75 or more based on 4.0 maximum).

Applications found to be responsive to the announcement shall be considered; those found to be unresponsive shall not be considered. A letter from CMBP Director will be sent to the grantee institution stating the reason for the outcome of the evaluation.

METHOD OF APPLYING

In lieu of submitting a form PHS 398, the Principal Investigator must submit a letter, countersigned by an authorizing official of the grantee institution, requesting support of a student for short-term laboratory training at the NCI.

This letter shall constitute an application and must include or be accompanied by the following:

- o A statement from the student that describes his/her research interests and career objectives and a brief resume;
- o Two letters of recommendation;
- o A current official college/university transcript;
- o The student's selection of three NCI laboratory choices prioritized by level of interest;
- o The title of the announcement;
- o A copy of the face page of the active MARC grant including the grant number and period of award; and
- o A description of the personnel to which the student shall report his/her NCI laboratory experience.

A list of NCI laboratory choices will be available to all applicants through the CMBP office.

Application packages must be received by the CMBP no later than February 1, 1992.

The 10-week training period may be between May 1992 and August 1992, inclusive. Under this announcement funding is available for this period only.

More than one supplemental application may be submitted by each grantee institution.

Supplemental applications to active MARC undergraduate training grants must be submitted directly to the CMBP, with a copy to the MARC program, at the addresses listed below:

INQUIRIES

Direct inquiries regarding programmatic issues to:

Program Director
Comprehensive Minority Biomedical Program
Division of Extramural Activities
National Cancer Institute
9000 Rockville Pike
Building 31, Room 10A04
Bethesda, MD 20892
Telephone: (301) 496-7344

Program Director
Minority Access to Research Careers
National Institute of General Medical Sciences
9000 Rockville Pike
Westwood Building, Room 9A18
Bethesda, MD 20892
Telephone: (301) 496-7941

Direct inquiries regarding fiscal matters to:

Ms. Carolyn Mason
Grants Management Specialist
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800, Extension 59

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.398 Cancer Research Manpower. National Institutes of Health, Public Health Service, Department of Health and Human Services Authorization: Public Health Service Act, Service 413, as amended by Public Law 99-158, 42 U.S.C. 288. Federal Agency: National Institutes of Health, Public Health Service, Department of Health and Human Services Authorization: Public Health Service Act, Section 301, Public Law 78- 410, 42 U.S.C. 241, and Section 412, as amended by Public Law 99.158, 42 U.S.C. 285a-1. Executive Order 12372 applicable.

STUDIES ON BREAST, PROSTATE, OVARIAN, AND CERVICAL CANCER

PA: PA-92-27

P.T. 34; K.W. 0715035, 0705075, 0413002, 0745020, 0745027, 0745070

National Cancer Institute

PURPOSE

The United States Congress included the following language in the Conference Report accompanying the Fiscal Year 1992 appropriation bill for Labor, Health and Human Services, Education and Related Agencies: "The conferees express their serious concern about the growing epidemic of breast and prostate cancer in the United States. The conferees urge, in the strongest way, that the National Cancer Institute make breast, prostate, ovarian, and cervical cancer its top priorities and treat these diseases with utmost urgency."

Despite significant strides in prevention, diagnosis, and treatment, cancer continues to be a leading cause of death. It has been estimated that approximately 500,000 people will die of cancer in the United States in 1991. It is estimated that 18 percent of this cancer mortality will be due to malignancies of the breast, prostate, ovary, and cervix. The National Cancer Institute (NCI) has devoted, and will continue to devote, significant resources to studies of these cancers. However, much remains to be accomplished so that more effective preventive, diagnostic, and therapeutic modalities can be established. This program announcement serves to notify and reaffirm to the scientific community the continuing commitment and interest of the NCI in expanding research support in basic and applied studies of the etiology, biology, diagnosis, treatment, and prevention of these specific cancers as a matter of high Institute priority.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Studies on Breast, Prostate, Ovarian, and Cervical Cancer, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-0325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Research grant applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged.

MECHANISMS OF SUPPORT

Support of this program will be by research project grants (R01), program project grants (P01), First Independent Research Support and Transition (FIRST) Awards (R29), Outstanding Investigator Grants (R35), and Method to Extend Research in Time (MERIT) Awards (R37). In addition, competing supplemental applications to active grants under these support mechanisms and research project cooperative agreements (U01), except for the FIRST Award, are specifically encouraged to pursue new promising avenues of research.

RESEARCH OBJECTIVES

The NCI is composed of four program Divisions that support extramural research relevant to this program announcement. The spectrum of research supported by these Divisions is as follows:

The NCI's Division of Cancer Etiology plans and directs a national program of basic research including laboratory, field, and epidemiologic and biometric research on the cause and natural history of cancer and means for preventing cancer, and evaluates mechanisms of cancer induction and promotion by chemicals, viruses, and environmental agents. Representative types of research activities appropriate to this program announcement include, but are not limited to, assessment of the relative contributions and interactions of lifestyle, environment, occupation, genetic factors, viruses, and/or metabolism on the risk of cancers of the breast, prostate, ovaries, and cervix. In addition, integrated multidisciplinary studies in chemical carcinogenesis are encouraged to identify epithelial cell markers for various stages of transformation, to identify inhibitors of carcinogenesis including natural inhibitors in the human environment, and to determine the specific molecular changes that occur as epithelial cells are transformed. Finally, studies are specifically solicited to identify protective epitopes of the human papillomaviruses associated with cervical carcinoma, that are necessary for the preparation, testing, and eventual production of protective or therapeutic vaccines for this form of cancer.

The Division of Cancer Biology, Diagnosis, and Centers supports research on the cellular and molecular biology of malignant cells, the role of the immune system in tumor growth and progression and on the transfer of basic research findings to clinical application for the improved diagnosis/prognosis of cancer. In the area of cancer biology, areas of emphasis include, but are not limited to: soluble factors (e.g., hormones, growth factors), and matrix and membrane macromolecules that modulate the growth of tumor cells; the regulation of the expression of these effectors and the mechanism of action; and the genetic events responsible for progression of tumors to a highly malignant and metastatic state. In the area of cancer immunology, specific interests include, but are not limited to: cellular and humoral immune recognition of tumor antigens, methods of improving immune killing of tumor cells, immune control of tumor metastasis, other regulatory effects of the immune system on tumor growth, and tumor modulation of host immune function. Studies are specifically solicited for further research in these areas of immunology aimed at the eventual development of vaccines for the primary or secondary prevention of these cancers. In the area of cancer diagnosis, areas of emphasis include, but are not limited to: more precise staging of tumors for prognostic and therapeutic decision making, more effective monitoring of response to therapy, earlier detection of both initial and recurrent tumors, and identification of populations at risk for developing particular cancers.

The Division of Cancer Prevention and Control plans, develops, directs, and coordinates research on prevention, control, and community oncology. Representative studies involve the identification and evaluation of agents that may inhibit carcinogenesis (initiation, promotion, transformation, and/or progression). These studies could include identification of appropriate agents through literature searches or laboratory methods, efficacy and toxicology studies in animals to aid in selection of materials for human studies, and phase I and II clinical trials of potential preventive agents. Other research could focus on reduction of cancer morbidity and mortality through early detection including identification of biological markers of risk, exposure, and pre-malignant events of progression. Research on the roles of nutrients, food groups, and other dietary components in cancer incidence is appropriate including the influence of dietary factors on the modulation of cancer risk markers or intermediate endpoints. Cancer control includes research on the development and testing of intervention strategies to modify personal, social, and lifestyle factors known to contribute to the development and/or increased risk of cancer, and multidisciplinary intervention research aimed at addressing minority, underserved, and other special populations. Research under the program announcement also may include data collection, statistical analysis and mathematical modeling, health services research, and information database linkage studies to monitor progress toward cancer control, particularly pertaining to the PHS "Healthy People 2000" National Goals.

The Division of Cancer Treatment plans, directs, and coordinates an integrated program of preclinical and clinical cancer treatment research with the objective of curing or controlling cancer in humans by utilizing single or combination treatment modalities. The tumors addressed by this program announcement currently require multimodality treatment for optimal management of all stages and presentations of disease, but these treatment methods cause serious morbidity and fail to cure most patients with advanced disease. In preclinical cancer treatment research, there is an urgent need to translate recent developments in the molecular biology of cancer into the discovery of new anticancer treatments whose actions will be highly specific for particular genes or gene products. Exciting areas that may be exploited include oncogenes such as the HER-2/neu oncogene in breast cancer, suppressor genes, signal transduction, cell cycle regulation, growth factors/receptors, metastasis, and angiogenesis. Several approaches will be necessary to take advantage of these new opportunities. Additional topics include, but are not limited to, drug discovery of new anticancer agents, biochemical and molecular mechanisms of antitumor drug action, and pharmacology and toxicology of antitumor agents. Studies to circumvent individual and multiple drug resistance and prevent metastasis of these cancers to other organs are included. Clinical research opportunities exist in the areas of high-dose chemotherapy followed by autologous bone marrow rescue, multidrug resistance, radiosensitizers, adjuvant chemotherapy, innovative surgical or multimodality approaches, particle beam irradiation, novel immune therapies and genetic manipulations of host or malignant tissues, therapy with biological products, such as interleukins, monoclonal antibodies, and/or retinoic acid. Applications that address these opportunities and these particular tumors are specifically solicited.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions that disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E. Human Subjects. Applicants/offers are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications must be submitted on the grant application form PHS 398 (rev. 10/88, reprinted 9/89) and will be accepted at the standard application deadlines as indicated in the application kit.

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, MD 20892, telephone 301/496-7441. The title and number of the announcement must be typed in line 2 on the face page of the application.

The completed original application and six legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by an appropriate national advisory council or board. Applications for supplements to ongoing awards will be reviewed according to procedures applicable to the mechanism of the ongoing award.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of this program announcement are encouraged and must be directed to the NCI Referral Office at the address below. The opportunity to clarify any issues or questions from potential applicants is welcome.

NCI Referral Office
Review Logistics Branch
Division of Extramural Activities
National Cancer Institute
Westwood Building, Room 850
Bethesda, MD 20892
Telephone: (301) 496-7173
FAX: (301) 402-0275

Inquiries will be referred to the appropriate NCI Program Director in one of the program Divisions noted above in the "Research Objectives" section of this announcement.

Direct inquiries regarding fiscal matters to:

Ms. Roslyn Bacon
Grants Administration Specialist
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
6120 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7800, extension 51
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance under one or more of the applicable sections: No. 93.393, No. 93.394, No. 93.395, No. 93.396, and No. 93.399. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ACADEMIC RESEARCH ENHANCEMENT AWARD

PA: PA-92-28

P.T. 34; K.W. 0710030, 0404000, 1014006

National Institutes of Health

Application Receipt Date: June 19, 1991

PURPOSE

The National Institutes of Health (NIH) is making a special effort to stimulate research in educational institutions that provide baccalaureate training for a significant number of the Nation's research scientists but that historically have not been major recipients of NIH support. Since Fiscal Year (FY) 1985, Congressional appropriations for the NIH have included funds for this initiative, the Academic Research Enhancement Award (AREA) Program (R15).

The AREA funds are intended to support new research projects or expand ongoing research activities proposed by faculty members of eligible institutions in areas related to the health sciences. Applications received in June 1991 for AREA grants to be awarded in FY 1992 are currently undergoing review for scientific merit. Since it is anticipated that additional funds will be available next year, the NIH is inviting grant applications at this time for AREA grants to be awarded competitively in FY 1993.

ELIGIBILITY

Applicant Institutions

- o All domestic institutions offering baccalaureate or advanced degrees in the sciences related to health are eligible, EXCEPT those that have received an NIH Biomedical Research Support Grant (BRSG) of \$20,000 or more per year for four or more years during the period from FY 1985 through FY 1991.
- o Health professional schools (e.g., schools of medicine, dentistry, nursing, osteopathy, pharmacy, veterinary medicine, public health, allied health, and optometry) as well as organizationally discrete campuses of a university system, are eligible if they meet the above criterion.
- o Several applications proposing different research projects may be submitted by an applicant institution.

Proposed Principal Investigators

- o Must not have active research grant support (including an AREA) from either NIH or the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) at the time of award of an AREA grant.
- o May not submit a traditional NIH or ADAMHA research grant (R01) application for essentially the same project as a pending AREA application.
- o Are expected to conduct the majority of their research at their own institution, although limited access to special facilities or equipment at another institution is permitted.
- o May not be awarded more than one AREA grant at a time nor be awarded a second AREA grant to continue the research initiated under the first AREA grant.

Those in doubt about eligibility should consult the Office of Sponsored Programs at the institution. Questions regarding eligibility, policies, procedures, and other administrative aspects of the NIH AREA Program that remain AFTER CONSULTATION WITH THE INSTITUTIONAL OFFICE may be addressed to: Research Training and Special Programs Office, NIH, Building 31, Room 5B44, Bethesda, MD 20892, telephone (301) 496-1968.

APPLICATION PROCEDURES

Applications for the AREA Program will be accepted under the application submission procedures of the Division of Research Grants (DRG), NIH. The research grant application form PHS 398, Revised 9/91, must be used in applying for an AREA grant.

Applicants must obtain the AREA Program Guidelines containing supplemental instructions for AREA applications from the Office of Grants Inquiries, DRG, NIH (see address below). These instructions must be followed in preparing an application.

AREA grants are awarded on a competitive basis. Applicants may request support for up to \$75,000 for direct costs (plus applicable indirect costs) for a period not to exceed 36 months. No more than \$35,000 may be requested for direct costs for any one year. Although this award is non-renewable, it will enable qualified individual scientists within the eligible institutions to receive support for feasibility studies, pilot studies, and other small-scale research projects preparatory to seeking more substantial funding from the NIH research grant programs.

REVIEW PROCEDURES

Applications for the AREA Program will be subjected to the standard peer review process involving two sequential levels of review. The first level of review is performed by initial review groups composed primarily of non-Federal scientists selected for their competence in particular scientific fields. The second level of review is made by the National Advisory Council or Board of the NIH awarding component to which the grant application has been assigned by the DRG. These groups are composed of both scientific and lay representatives who are chosen for their expertise, interest, or activity in matters related to the mission of the individual awarding component. Council or Board recommendations are based on both scientific merit and relevance to awarding component program goals. In general, the NIH may award a grant only if the corresponding application has been recommended for funding by both levels of review.

AWARD DETERMINATION

Funding decisions will be based on the proposed research project's scientific merit and relevance to NIH programs and the institution's contribution to the undergraduate preparation of doctoral-level health professionals. Among projects of essentially equivalent scientific merit and program relevance, preference will be given to those submitted by institutions that have granted baccalaureate degrees to 25 or more individuals who have obtained academic or professional doctoral degrees in the health related sciences during the period 1982-1991.

SUPPLEMENTAL INSTRUCTIONS/APPLICATION FORMS

Those individuals and institutions meeting the eligibility requirements may contact the office named below to receive the AREA Program Guidelines and/or form PHS 398 application packages. (NOTE: Form PHS 398, Revised 9/91, is currently being printed. It should be available in institutional business offices and from the NIH by March 1992.)

AREA
Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building, Room 449
Bethesda, MD 20892
Telephone: (301) 496-7441

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.390. Grants will be awarded under authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered in accordance with the PHS Grants Policy Statement and Federal Regulations at 42 CFR Part 52 and 42 CFR Part 74.

INTERACTIVE RESEARCH PROJECT GRANTS FOR CANCER

PA: PA-92-29

P.T. 34; K.W. 0715035, 0710070, 0760025, 0745027, 0755015, 0755025

National Cancer Institute

Application Receipt Dates: February 1, June 1, and October 1

PURPOSE

Complex questions in cancer research often require investigative efforts that extend beyond the level practicable in a single project or that require a mixture of technical approaches beyond the means of a single investigator. The perceived merit of individual research project (R01) applications sometimes may be limited by the lack of a comprehensive, interdisciplinary approach, or by limitations in resident technical expertise. There also may be areas of investigation that are under-represented in applications because they cannot effectively be exploited without a collaborative effort, yet local opportunities for such interactions are not available.

The National Cancer Institute (NCI), under an Interactive Research Project Grant (IRPG) announcement, seeks to encourage the coordinated submission of related research project grant applications from investigators who want to collaborate on a common cancer research theme, but do not require extensive shared physical resources or core functions. A minimum of three independent investigators with related research objectives are encouraged to submit concurrent, collaborative, cross-referenced individual research project grant applications (R01) that share a common research focus. Applications may be from either a single institution or a consortium of

institutions. Applications will be reviewed independently for scientific merit. Meritorious applications will be considered for funding both as independent awards and in the context of the overall proposed collaboration.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Interactive Research Project Grants for Cancer, is related to the priority area of cancer. Potential applicants may obtain a copy of a "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

BACKGROUND INFORMATION

Historically, the NCI has relied on multi-component awards, such as program projects (P01) and Cancer Center Support grants (P30), to encourage interdisciplinary collaborations in areas requiring integration and central direction of basic and clinical research components. A hallmark of such awards is the provision for extensive core facilities/resources and appointment of a program director to manage the overall effort.

For many research areas it may be more appropriate to consider an intermediate level of collaboration, less extensive than that described above, but beyond that practical for single projects. For such intellectually driven collaborative efforts, the exchange of data, materials, and ideas, rather than shared physical resources or central oversight, is the primary requirement. The concept of IRPGs set forth in this announcement is meant to address and facilitate this class of research activities. Typically, the IRPG approach will be suited to many basic research questions as well as research to develop, apply, and evaluate interventions for cancer prevention and control. The IRPG mechanism may also fit well with clinical applications that propose limited testable research questions or with focused phase I and II therapeutic and related correlative laboratory studies.

Applicants will benefit from use of the IRPG mechanism by establishing a larger framework of reference for the proposed work, by facilitating formal collaborations tailored to achieving research objectives, by providing a record of independently acquired awards credited to each funded investigator, and by allowing retention of research autonomy by the named Principal Investigator on each of the interactive grants. Each grantee will have the ability to submit on his/her own behalf competing supplements as appropriate to incorporate promising new directions of research as they evolve. The freedom to establish collaborations on an equal footing at separate sites (including foreign locations), and the improved transferability of awards made to individual Principal Investigators, also are significant benefits. In contrast, translational research programs that span a variety of disciplines and programs that require extensive co-located core resources, would continue to be served best by traditional multi-component program award mechanisms.

RESEARCH GOALS AND SCOPE

The NCI encourages qualified investigators to develop and submit concurrently coordinated research project applications that address areas of relevance to cancer in which the interactive research project concept may be applied. Applications submitted as a package should be tightly focused and the interactions and benefits of the proposed linkages should be made explicit as explained below.

IRPG applications will be accepted in any relevant area of cancer research where this mechanism may be constructively applied. Some typical (non-exhaustive) examples are cited below:

- o Immunobiology of specific cancers, such as breast, ovarian, and prostate cancer. Since these cancers involve both immune and neuroendocrine responses, projects requiring expertise in various aspects of cancer biology, immunology, and/or endocrinology will be needed for a comprehensive approach for these questions.
- o Hormones and signalling pathways. Basic science projects may be combined that integrate multiple aspects of hormonal regulation of cancer from growth factors to receptors to signal transduction to genetic regulation.
- o Detection and intervention studies in breast and other cancers. New methods are needed to promote the use of detection methodologies in populations at risk and to measure the efficacy and compliance with recommendations. Studies to identify and overcome barriers to health promotion and to measure cost-effectiveness may also be linked to such a program.
- o Focused studies on phase I and II clinical trials. Projects designed to investigate promising combined therapeutic approaches to a single type of cancer may be linked with correlative laboratory investigations to investigate further the mode of action and/or biological effects of treatments.
- o Related basic studies focused on multiple facets of common viral or chemical carcinogenic agents such as HIV or human papilloma virus, that do not require extensive core resources.
- o Basic drug discovery programs that focus on multiple aspects of a related class of compounds or on a single mechanism of action.
- o Methodologically related applications that focus on development and/or application of specific methodologies to cancer research, where extensive shared physical resources are not required.

o Research on variations in control of the cell cycle that operate specifically in tumor cells. Projects might focus on unique enzymes or effector molecules, the role of protein modifications such as phosphorylation, activation of oncogenes, and interactions with suppressor genes.

Prospective applicants are encouraged to explore other areas of potential for the IRPG mechanism with NCI program directors.

MECHANISM OF SUPPORT AND SPECIAL INSTRUCTIONS

Support of this program will be by the research project (R01) grant. Applicants will be responsible for the planning, direction, and execution of the proposed projects. One Principal Investigator out of the group MUST be identified as the "Program Coordinator," and must be cited in all applications on page 2 of form PHS 398. Individual investigators may request funds for the time and effort contributed toward the coordination of the overall research and for collaborative resource activities.

Each application MUST be complete in itself, with all appropriate approvals, budgets, and signatures. Each application MUST be identified by checking "yes" on line 2 of the PHS 398 face page and citing this announcement, "Interactive Research Project Grants for Cancer, PA-92-XX."

The use of the IRPG mechanism must be mentioned briefly in form PHS 398, Sections A-D of the Research plan. The goal of the collaborative efforts MUST be identified in the specific aims of each application, with the major rationale and explanation for the use of the IRPG mechanism to be given in Section G, Consultants/Collaborators. A complete list of applications in the IRPG must be provided in Section G, as well as an indication of the specific collaborations to be established for the individual application under consideration.

Requests for limited shared resources, if any, must be proportionally budgeted in each application based on anticipated use, with a full explanation given in the budget. Personnel Time and Effort requests for management of shared resources are allowable. If consortium arrangements between independent institutions are proposed that would make transfer of funds for required new equipment impractical, the entire equipment request may be budgeted by the responsible laboratory. This should be clearly justified.

All PHS and NIH grants policies will apply to applications received in response to this announcement.

ELIGIBILITY REQUIREMENTS

Domestic and foreign non-profit and for-profit organizations and institutions, governments and their agencies, are eligible to apply. Applications may be submitted from a single institution or may include arrangements with multiple institutions if appropriate. Applications from or involving minority institutions, individuals, and women are encouraged.

Each application will be considered on its own merit as an individual research project. Therefore, applicants for IRPGs MAY NOT concurrently submit R01 applications that represent significant duplication of the efforts described in the applicant's IRPG. In this regard, it should be noted that the NCI will consider funding meritorious individual IRPG applications if it is not possible to fund the IRPG package as a whole. Concurrent submission of program project (P01) applications that request support for essentially similar work is also prohibited.

REVIEW PROCEDURES

Upon receipt, applications and supporting material will be reviewed by the Division of Research Grants for completeness. Incomplete applications will be returned without further consideration. Each application will be assigned to an institute on the basis of the scientific subject matter of the application. Therefore, to be eligible for the NCI IRPG program, an application MUST meet the PHS referral guidelines to receive assignment to the NCI. APPLICANTS ARE STRONGLY ENCOURAGED TO CONSULT WITH NCI PROGRAM STAFF PRIOR TO SUBMISSION TO ENSURE THAT THE APPLICATION CONFORMS TO THESE GUIDELINES, AND THAT THE IRPG MECHANISM IS AN APPROPRIATE CHOICE.

Complete applications will be reviewed for scientific and technical merit by an appropriate peer review group convened by the Division of Research Grants, NIH. Insofar as possible, assignment of each IRPG application will be to a standing DRG initial review group, that may be supplemented by consultants with additional expertise as required. Investigators should be aware that applications utilizing widely differing approaches will not necessarily be reviewed by the same initial review group. Attention in selecting clearly related applications for submission will aid the process of assignment for review.

Initial review groups will employ standard peer review criteria that pertain to all individual research project applications. Following peer review, the applications will receive a second-level review by the National Cancer Advisory Board or other appropriate national advisory council or board.

Although there is no fixed set-aside of funds committed to the IRPG mechanism, the NCI will consider for funding all IRPG applications in a cohort if all are rated by peer review as having significant and substantial scientific merit.

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study populations must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans including American Indians or Alaskan Natives, Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign populations groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants that do not comply with these policies.

METHOD OF APPLYING

The research grant application form PHS 398 (rev. 10/88) must be used in applying for these grants. Applications will be accepted on the February 1, June 1, and October 1 receipt dates. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, Bethesda, MD 20892; and from the NCI Program Director named below. The Program Announcement title and number must be typed on line 2 of the face page. Submit a signed, typewritten original of each application and six signed exact single-sided photocopies to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

**THE MAILING ADDRESS FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NIH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:

5333 Westbard Avenue
Bethesda, Maryland 20816

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of this Program Announcement and inquiries about whether or not specified proposed research would be appropriate for this mechanism are encouraged and may be directed to:

NCI Referral Officer
Review Logistics Branch
Division of Extramural Activities
National Cancer Institute
Westwood Building, Room 850
Bethesda, MD 20892
Telephone: (301) 496-7173
FAX: (301) 402-0275

Callers will be referred to the appropriate NCI Program Director.



Inquiries regarding fiscal matters may be directed to:

Ms. Roslyn Bacon
Grants Management Specialist
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
6120 Executive Blvd.
Bethesda, MD 20892
Telephone: (301) 496-7800, extension 51
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance under one or more of the applicable sections: No. 93.393, No. 93.394, No. 93.395, No. 93.396, and No. 93.399. Awards are made under the authorization of the Public Health Service Act, Sections 301, 410, and 411 (Public Law 78-410, 42 USC 241 as amended, Public Law 99-158, 42 USC 285a) and administered under PHS grants policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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NOTICES OF AVAILABILITY (RFPs AND RFAs)RETINAL ARTERY READING CENTER FOR THE ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

RFP AVAILABLE: NHLBI-HC-92-09

P.T. 34; K.W. 0715040, 0705070, 0411005

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) requires a reading center to interpret retinal photographs performed in the epidemiological research study of the major factors contributing to the occurrence of cardiovascular disease in middle-aged adults entitled "Atherosclerosis Risk in Communities Study (ARIC)." The Retinal Artery Reading Center will assist in protocol development for the performance of retinal artery examinations in 14,500 participants in the four ARIC Field Centers and will perform measurements and interpretations of these images in a standardized and reproducible manner. The period of performance is anticipated to be November 1, 1992 through October 31, 1996.

This is a notice of availability of a Request for Proposals (RFP). RFP NHLBI-HC-92-09 will be available on or about January 15, 1992, with proposals due February 21, 1992. One award is anticipated to be made during October 1992. A written request for the RFP must include three mailing labels, self-addressed, and must cite RFP No. NHLBI-HC-92-09.

Requests for copies of the RFP are to be sent to the following address:

Donna J. Neal
Contract Specialist
ECA Section, Contracts Operations Branch, DEA
National Heart, Lung, and Blood Institute
Federal Building, Room 3C16
7550 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-1326

EVALUATION OF IMMUNE-BASED THERAPIES FOR AIDS USING ANIMAL MODELS

RFP AVAILABLE: NIAID-DAIDS-92-15

P.T. 34; K.W. 0715008, 0745045, 0755020

National Institute of Allergy and Infectious Diseases

The Developmental Therapeutics Branch, Basic Research and Development Program, Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID), has a requirement for the evaluation of immune-based therapies for AIDS using animal models. This procurement consists of two parts that seek testing capabilities for immune-based therapies that target different types of immune deficiencies seen in HIV infection and AIDS. The two parts are entitled, "Part A - Evaluation of Immune-Based Therapies to Augment or Normalize Immune Function" and "Part B - Evaluation of Multipotent Stem Cell Reconstitution as a Therapy to Restore Immune Cell Deficits".

"Part A" of this procurement will provide for the evaluation of immune-based therapies in an established small-animal model, alone or in combination with other therapies, for their capacity to augment host-defense mechanisms or otherwise ameliorate immune dysfunctions characteristic of HIV infection. Emphasis will be placed on aspects of immune-based therapies, i.e., mechanism of action, optimal scheduling, identification of quantifiable parameters related to in vivo efficacy, potential for positive or negative interaction between immune-based and anti-retroviral therapies, and the potential of immune-based therapies to upregulate virus expression. An established and validated animal model is required for Part A. "Part B" of this procurement will provide for development, validation, and testing of a model in which an immunodeficient animal is reconstituted with a source of human multipotent stem cells that can re-establish the immune system and that may also be genetically modified to resist subsequent infection with HIV-1.

The offeror shall, at the time of proposal, have identified an animal system to be developed and validated and a source of human multipotent stem cells. These capabilities are required by the Division of AIDS, NIAID, in its efforts to develop immune-based therapies for human subjects infected with HIV-1. There will be separate work statements and competitive ranges established for each part. Offerors may respond to one or more parts. It is anticipated that one or more awards will be made for Part A and one award will be made for Part B. If more than one award is made for Part A, the Government reserves the right to make only one award per animal model. This NIAID-sponsored project will take approximately five years to complete. A cost-reimbursement contract is anticipated.

This is an announcement for an anticipated Request for Proposal (RFP). RFP NIAID-DAIDS-92-15 shall be issued on or about January 20, 1992, with a closing date tentatively set for March 20, 1992. Requests for the RFP shall be directed in writing to:

Cyndie Cotter
Contract Management Branch
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3C-07
6003 Executive Boulevard
Bethesda, MD 20892

To receive a copy of the RFP, supply this office with two self-addressed labels. All responsible sources may submit a proposal that will be considered.

This announcement does not commit the Government to award a contract.

DOMESTIC ANIMAL MODELS FOR RETROVIRUS-ASSOCIATED HUMAN CANCERS

RFA AVAILABLE: CA-92-07

P.T. 34; K.W. 0755020, 0755030, 1002045, 0715035, 0740012

National Cancer Institute

Letter of Intent Receipt Date: February 28, 1992
Application Receipt Date: April 28, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

Retroviruses isolated from mammalian species have the potential to provide valuable basic information on the etiology and mechanism(s) of cancer induction by viruses and to serve as models for evaluating antiviral agents prior to human clinical trials. The occurrence of neoplastic sequelae in retrovirus-infected animals supports the view that these viruses may be directly or indirectly involved in the etiology of malignancies. The identification and development of suitable animal models of viral neoplasia may aid in investigations of the mechanisms of cancer initiation and progression, ultimately providing a better understanding of the role of viruses in the etiology of human cancer. The Congress, in both FY90 and FY92, has expressed its interest in retroviral infections in large domestic animals as excellent models for retroviral-induced diseases in humans such as leukemia, lymphosarcoma, and AIDS.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Domestic Animal Models for Retrovirus-Associated Human Cancers, is related to the priority area of cancer etiology. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Non-profit and for-profit, domestic and foreign, organizations and institutions, governments and their agencies are eligible to apply. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health (NIH) individual research grant (R01). Applicants will be responsible for the planning, direction, and execution of the proposed project. Except as otherwise stated in this RFA, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 90-50,000, revised October 1, 1990.

This RFA is a one-time solicitation. Future unsolicited competitive continuation applications will compete with all investigator-initiated applications and be reviewed by the Division of Research Grants (DRG). If, the National Cancer Institute determines that there is a sufficient continuing program need, a request for competitive continuation applications will be announced. Only recipients of awards under this RFA will be eligible to apply.

FUNDS AVAILABLE

Approximately \$1,750,000 in total costs per year for four years will be committed to specifically fund applications submitted in response to this RFA. It is anticipated that five to seven awards will be made. The level of funding is dependent on the receipt of a sufficient number of applications of high scientific merit. The total project period for applications submitted in response to the present RFA may not exceed four years. The earliest feasible start date for the initial awards will be September 1992. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The objectives of the RFA are to encourage basic research on retroviral pathogenesis in domestic livestock animals. These studies will aid in understanding the properties of viruses and features of the host and its response that determine disease progression from initial virus infection to neoplastic sequelae. For the purposes of this RFA, domestic animals include cows, horses, sheep, goats, and pigs; specifically excluded are retroviruses of dogs, cats, primates, and avian species. Collaborative efforts between scientists with complementary areas of research expertise will be encouraged. The areas of proposed investigation include: (1) investigations of the oncogenic mechanisms in domestic livestock retroviruses; (2) investigation of cancer etiology and viral pathogenesis from initial infection through the development of pre-neoplastic lesions and neoplastic sequelae with retroviruses of domestic livestock; (3) the role of RNA and DNA viral co-factors in cancer etiology animal models and definition of virus- and co-factor-host interactions and immune function alterations in the host that dispose the host to neoplastic processes; (4) investigations to assess the role of the host immune system and host genetic factors in the control and limitation of virus replication, and the susceptibility or resistance of animals to oncogenic processes; and (5) studies on the expression and regulation of viral and/or associated host cell genes in pre-neoplastic lesions and malignant tissues from retrovirus-infected domestic livestock animals.

LETTER OF INTENT

Prospective applicants are asked to submit, by February 28, 1992, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is requested in order to provide an indication of the number and scope of applications to be

reviewed. It also allows NCI staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Dr. Kenneth J. Cremer
Program Director, AIDS Virus Studies
Biological Carcinogenesis Branch
Division of Cancer Etiology
National Cancer Institute
Executive Plaza North, Room 540
Bethesda, MD 20892
Telephone: (301) 496-6085

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 10/88, reprinted 9/89) must be used in applying for these grants. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, Maryland 20892, telephone 301/496-7441; and from the NCI Program Director named above.

Applications must be received by April 28, 1992. If an application is received after that date, it will be returned to the applicant. The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Those applications judged to be both competitive and responsive will be further evaluated according to the review criteria stated below for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NCI. The second level of review by the National Cancer Advisory Board considers the special needs of the Institute and the priorities of the National Cancer Program.

1. The scientific merit, technical and medical significance of the proposed research, including the adequacy and quality of the methodological approach and the research design. Familiarity with the proposed techniques must be demonstrated, e.g., by the presentation of preliminary data.
2. The expertise and qualifications of the Principal Investigator and proposed staff and/or collaborators to perform the proposed experiments.
3. Documentation of the adequacy of the facilities and resources.
4. Appropriateness of the proposed budget and duration in relation to the proposed research.

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of this RFA and inquiries about whether or not specific proposed research would be responsive are encouraged and may be directed to Dr. Kenneth Cremer at the above address. The Program Director welcomes the opportunity to clarify any issues or questions from potential applicants and will provide a copy of the RFA on request.

Direct inquiries regarding fiscal matters to:

Mr. Joseph H. FitzGerald
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800, Ext. 15

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.393, Cancer Cause and Prevention Research. Awards are made under the authorization of the Public Health Service (PHS) Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 U.S.C. 241 and 285) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

HITCHINGS-ELION POSTDOCTORAL FELLOWSHIPS FOR U.S. SCIENTISTS

PA: PA-92-30

P.T. 22, 48, K.W. 0720005, 040400

Fogarty International Center

Application Receipt Dates: January 10, May 10, and September 10 of each year

PURPOSE

The purpose of these fellowships is to promote scientific collaboration between British and American scientists for the conduct of biomedical and behavioral research. The Hitchings-Elion Fellowships will support two years of collaborative research by a U.S. scientist at a sponsor's laboratory in the United Kingdom and a third year at a sponsor's laboratory in the United States.

BACKGROUND AND OBJECTIVES

The Hitchings-Elion Fellowships, named after the 1988 Nobel Laureates in Physiology and Medicine, provide support to U.S. scientists, early in their career, for the conduct of collaborative research in the United Kingdom. The program, which is a collaboration between The Wellcome Trust, The Burroughs Wellcome Fund and the Fogarty International Center (FIC), National Institutes of Health, provides fellowship support for three years: two years in the United Kingdom and a third in a laboratory in the United States. The types of activity supported by these programs include collaboration in basic or clinical research and familiarization with or utilization of special techniques and equipment not otherwise available to the applicant. The programs do not provide support for activities that have as the principal purpose brief observational visits, attendance at scientific meetings, or independent study. Research directly related to cancer is supported by other mechanisms in the United Kingdom and, therefore, is not eligible for support by this fellowship.

ELIGIBILITY

The applicant must be a U.S. citizen or permanent U.S. resident, hold a doctorate level degree in one of the medical or veterinary clinical, behavioral, or biomedical sciences, and be within ten years of the last doctoral degree.

ELIGIBLE COSTS

The Wellcome Trust will provide an annual stipend allowance with a base rate beginning at 13,661 pounds, that increases with years of experience to a maximum of 20,868 pounds, an additional yearly allowance depending on location in the United Kingdom, a special allowance for those working in London, research expenses (5,000 pounds per annum) while in the United Kingdom, round trip economy class air fare expenses for the fellow and up to three dependents, and a stipend for one year upon return to the United States at a level comparable, but not necessarily equivalent, to that received in the United Kingdom. The Burroughs Wellcome Fund will provide \$7,500 per annum for research expenses in the United States. For U.S. government employees, the third year of support will not be available in the United States. Indirect costs will not be provided in either the United Kingdom or the United States.

REVIEW PROCEDURE AND CRITERIA

The administration of the program will be integrated into the administration of other Fogarty International Center fellowship activities and the application receipt processes of the Division of Research Grants, NIH. The initial review of applications will be conducted by a special FIC study section. Application kits and information may be obtained from the Fogarty International Center at the address listed below. In addition to biographical data, references, and letters of invitation from the United Kingdom and U.S. sponsors, a description of the proposed activities in the United Kingdom and the U.S. and the benefit expected of the experiences will be required. While it is the applicant's responsibility to arrange for his or her research program with the United Kingdom and U.S. sponsors, it may be done directly or through correspondence by a senior U.S. scientist. In the United Kingdom, host institutions may include universities or government laboratories.

AWARD CRITERIA

Funding decisions will be made on the basis of the quality of the application as determined by peer review. Final decisions on awards will be made and announced by The Wellcome Trust.

METHOD OF APPLYING

Applications must be sent to the Division of Research Grants, NIH, to meet receipt dates of January 10, May 10 and September 10 each year. Special application forms must be used and are available, along with detailed instructions, from:

International Research and Awards Branch
Fogarty International Center
National Institutes of Health
Building 31, Room B2C39
Bethesda, MD 20892
Telephone: (301) 496-1653
FAX: (301) 402-0779

INQUIRIES

Questions concerning the application, review and award process may be referred to:

Dr. David Wolff
Chief, International Research and Awards Branch
Fogarty International Center
Building 31, Room B2C21
Bethesda, MD 20892
Telephone: (301) 496-1653
FAX: (301) 402-0779

NATIONAL RESEARCH SERVICE AWARDS FOR INSTITUTIONAL TRAINING GRANTS

PA AVAILABLE: PA-92-31

P.T. 44; K.W. 0720005, 0404003, 0404009, 0715095

Alcohol, Drug Abuse, and Mental Health Administration

Application Receipt Date: May 10

The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) announces the availability of a program announcement for National Research Service Awards for Institutional Training Grants.

AUTHORITY AND PURPOSE

Under authority of Section 487 of the Public Health Service Act as amended (42 USC 288), the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) provides National Research Service Awards (NRSAs) to eligible institutions to develop or enhance predoctoral and/or postdoctoral alcohol, drug, and/or mental health (ADM) research training opportunities for individuals who are training for careers in specified areas of biomedical and behavioral research. The proposed training must be in areas that encompass concepts and methods of the relevant disciplines, including basic and clinical sciences, and be of sufficient depth to enable the trainees, upon completion of the program, to formulate research projects and pursue careers as investigators. The support of institutional NRSAs (T32s) is to help ensure that highly trained scientific personnel will be available in adequate numbers and in the appropriate research areas and fields to meet the Nation's alcohol, drug abuse, and mental health research needs.

Each ADAMHA Institute has different program goals and initiatives; therefore, potential applicants must contact the appropriate Institute office, listed below, prior to preparing an application to obtain the full Program Announcement and current information about that Institute's interests with regard to T32s.

ELIGIBILITY REQUIREMENTS

Domestic public and private, non-profit institutions may apply. The applicant institution must have a strong, demonstrated research program in the area(s) proposed for research training.

The NRSA legislation requires, in making NRSAs, that the Nation's overall need for biomedical and/or behavioral research personnel be taken into account by giving special consideration to physicians who agree to undertake a minimum of two years of training in biomedical and/or behavioral research.

TRAINING PROGRAM AND TRAINEE REQUIREMENTS

The training program director at the institution will be responsible for selection and appointment of individuals to receive NRSAs and for the overall direction of the research training program. The training program must provide opportunities for individual trainees to carry out supervised research in the specified areas with the primary objective of extending their skills and knowledge in preparation for a research career. Special attention must be given to the appointment of minority students and women.

Trainee Requirements: Individuals selected for NRSAs must be citizens or noncitizen nationals of the United States or have been lawfully admitted to the United States for permanent residence and have in their possession an Alien Registration Receipt Card (I-151 or I-551) at the time of appointment to the training program. Predoctoral applicants must have received a baccalaureate degree and be enrolled in a doctoral degree program at the time of appointment. Postdoctoral individuals selected to receive NRSAs must have received a Ph.D., Psy.D., M.D., D.D.S., D. Pharm., D.N.S., D.S.W., or equivalent domestic or foreign degree from an accredited institution as of the date of appointment. Certification by an authorized official of the degree-granting

institution that all degree requirements have been met is also acceptable. NRSAs are not made for study leading to the M.D., D.O., D.D.S., or other similar professional degrees nor do they support residency training.

SPECIAL INTERESTS

Research Recruitment: Support is available for three to four months of research involvement for clinicians and graduate students interested in exploring an ADM research career. Research recruitment candidates are not subject to the NRSA payback requirement.

Short-term Research Training: This is a brief reference to a separate announcement titled, "Short-term National Research Service Awards for Institutional Grants," presently being developed. Special conditions apply; therefore, potential applicants must contact one of the institute offices listed below for guidance.

APPLICATION CHARACTERISTICS AND PERIOD OF SUPPORT

Applicants for institutional NRSAs must follow the instructions accompanying the current version of grant application form PHS 398 (revised 10/88) that contains special instructions for institutional NRSAs. Applicants for research training grants wishing to include a request for a research recruitment training program must also use the instructions for Institutional Research Training Grants included with the form PHS 398. The number and title of this announcement "PA-92-31, NRSA for Institutional Awards" must be typed on line 2. Requests for recruitment positions must be identified as a separate category on the budget page listing the number of candidates, the total stipend amount, and the total amount of the training-related expenses. The description of the research recruitment training program must be included in the application for the research training program but must be separated from the description of the research training program within each section of the application. The applicant must address the relationship of the proposed recruitment program to the research training program, providing assurance that the research recruitment program will not detract from the training program. Applicants must observe the page limits specified in the PHS 398 instructions.

The form PHS 398 is usually available from institutional offices of sponsored research or their equivalent. If not available locally, it may be obtained from the offices listed at the end of this announcement. Every application must include the following information about the training program:

- o All new research training grant applications are required to have a plan for recruitment of minority trainees. Competing renewal applications are required to include a list of accomplishments in recruitment, retention, and progress of minority students achieved in the prior project period in addition to recruitment plans in the next project period. Applications without a minority recruitment plan and, for the renewal applications, a report of accomplishments in recruiting minority trainees will not be reviewed until these items are received.
- o All competing applications must include evidence that training in the principles of responsible scientific conduct will be incorporated into the research experience of each trainee. Applications without plans to provide such instruction will not be awarded until a plan is received.
- o Applications must include discussion of the relevance of the proposed training program to the manpower needs of the relevant scientific area.

Funding Criteria: Awarding components select applications for funding primarily on the basis of scientific merit review results, but other factors may be considered such as: availability of funds, research program priorities specified in the Attachment to the full program announcement, balance among types of research training supported by the awarding component, and minority recruitment efforts.

Period of Support: Awards for institutional grants may be made for project periods of up to five years. By law, an individual may receive no more than five years of NRSA support in the aggregate at the predoctoral level and three years of support in the aggregate at the postdoctoral level under the NRSA program, including any combination of support from individual and institutional awards.

APPLICATION RECEIPT AND REVIEW SCHEDULE

ADAMHA institutional training applications have only one receipt date, May 10. Applications received after the May 10 receipt date are subject to assignment to the next review cycle or may be returned to the applicant without review if requested by the applicant. The applications will receive an October peer review by the appropriate initial review group and review by the appropriate Advisory Council in January/February.

Eligible institutions desiring to request support under this program are encouraged to review the research areas specified in the Attachment to the full program announcement before requesting application kits. The complete announcement and the attachment are available from the offices listed below. An original and six copies of the completed and signed application are to be submitted to the Division of Research Grants, 5333 Westbard Avenue, Room 240, Bethesda, Maryland 20892 (applicants using express mail or courier services should use the 20816 zip code).

REVIEW PROCESS AND CRITERIA, AND OTHER CONSIDERATIONS

Institutional training grant applications are reviewed for scientific and educational merit by ADAMHA initial review groups composed primarily of nongovernment scientists and are also subject to the review and recommendations of the appropriate ADAMHA Advisory Council. Major considerations in the review are the following: the qualifications of participating faculty, their success in previous training endeavors and the

research context in which the training program will be established; the breadth, depth, and quality of the training program; the plans for recruiting and selecting trainees; and the adequacy of the training facilities and resources. Detailed criteria are listed in the full announcement.

CONDITIONS OF AWARD

Grants must be administered in accordance with the PHS Grants Policy Statement. Before a trainee can be appointed to an NRSA institutional grant, he or she must meet NRSA eligibility requirements and sign a Payback Agreement indicating his or her intent to meet the payback provisions required under the law. Institutions shall notify prospective trainees of these provisions prior to or at the time an appointment is offered. The Payback Agreement form must be completed and submitted to the awarding institute immediately upon appointment of a new trainee.

Payback Requirement: Recipients of stipends under institutional NRSAs must agree to engage in health-related research and/or teaching for a period equal to the period of NRSA support in excess of 12 months. Activities carried out while supported by NRSAs may not be used to fulfill the payback requirements.

The institution must submit to ADAMHA a Statement of Appointment form (PHS 2271) along with the signed Payback Agreement each time a trainee is appointed or reappointed to the grant. At the end of the total support period for each individual trainee, the institution must submit a Termination Notice (PHS 416-7) to ADAMHA. Trainees are required to pursue their research training on a full-time basis, devoting at least 40 hours per week as specified by the sponsoring institution in accordance with its policies. An NRSA may not be held concurrently with another federally sponsored fellowship or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA. An awardee may accept concurrent educational remuneration from the Veterans Administration and loans from Federal funds.

STIPENDS AND RELATED COSTS

The annual stipend for predoctoral individuals at all levels, as of December 1991, is \$8,800. For postdoctoral individuals, a stipend is determined on the basis of the number of years of prior relevant postdoctoral experience. This determination is made at the time of each appointment or reappointment of an individual. Postdoctoral stipends are:

Years of relevant experience	Annual stipend	Years of relevant experience	Annual stipend
0	\$18,600	4	28,200
1	\$19,700	5	29,500
2	\$25,600	6	30,800
3	\$26,900	7 or more	32,300

The Tax Reform Act of 1986, Public Law 99-514, describes the tax liability of all individuals supported under the NRSA program. The interpretation and implementation of the tax laws are the domain of the Internal Revenue Service (IRS) and the courts. The IRS should be consulted to clarify the applicability of the tax laws to individual trainee situations and to determine what steps must be taken to fulfill tax obligations.

The institution may request funds for tuition, fees, and certain types of travel for trainees; actual indirect costs or 8 percent of allowable direct costs (whichever is less) to cover related institutional overhead; and up to \$1,500 per predoctoral individual and \$2,500 per postdoctoral individual for other related costs (e.g., salaries, equipment, research supplies). Research recruitment positions will be prorated. Tuition at the postdoctoral level is limited to that required for specified courses in support of the approved training program. Applicants may request additional trainee-related expenses (not to exceed \$3,000 for predoctoral and \$5,000 for postdoctoral trainees) when the nature of the program requires exceptional support.

INQUIRIES

The full Program Announcement and Attachment, up-to-date policy guidelines, and the application forms may be obtained from any of the following offices:

National Institute on Alcohol Abuse and Alcoholism
Office of Scientific Affairs
5600 Fishers Lane, Room 16C20
Rockville, MD 20857
Telephone: (301) 443-4375

National Institute on Drug Abuse
Office of Extramural Program Review
5600 Fishers Lane, Room 10-42
Rockville, MD 20857
Telephone: (301) 443-2755

National Institute of Mental Health
Division of Extramural Activities
5600 Fishers Lane, Room 9-105
Rockville, MD 20857
Telephone: (301) 443-3367

Inquiries regarding grants management may be directed to:

Grants Awards and Operations Section
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C05
Rockville, MD 20857
Telephone: (301) 443-4414

MINORITY SCHOOL FACULTY DEVELOPMENT AWARD

PA: PA-92-32

P.T. 14, FF; K.W. 0715035, 0710030

National Cancer Institute

Application Receipt Dates: February 1, 1992, June 1, 1992, October 1, 1992

PURPOSE

The Comprehensive Minority Biomedical Research Program, Division of Extramural Activities, National Cancer Institute (NCI), invites academic health centers and other health professional schools that employ, educate, or serve a preponderance of minority faculty, staff, trainees, and communities to submit applications for support of activities directed at the development of faculty investigators at minority schools in areas relevant to cancer. The intent of the award is to provide the awardee with increased access to research opportunities through collaborative arrangements with outstanding cancer research scientists, usually at institutions within a 100 mile radius of the applicant organization.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Health People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Minority School Faculty Development Award, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Health People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY

Minority School

A minority school is defined as a medical or nonmedical college, university, or equivalent school in which students of minority ethnic groups, including African Americans, Hispanics, American Indians, and Asian or Pacific Islanders, comprise a significant proportion of the school enrollment and that has a commitment to the special encouragement of minority faculty, students, and investigators.

Faculty Development Award Candidate

Candidates for this award are minority school faculty members who: (1) are citizens of the United States, noncitizen nationals or permanent residents at the time of application; (2) have a M.D., Ph.D., or equivalent degree, in a biomedical or behavioral science; (3) wish to receive specialized training in cancer research; and (4) have the background and potential to become an independent biomedical investigator. A minimum of 50 percent effort annually must be committed to the award.

Applicants may not apply for, or accept, other PHS research grant support or its equivalent at the time of Minority School Faculty Development Award application, nor may they apply concurrently for any other type of academic award. However, applicants may apply for and accept research grant support subsequent to award of the Minority School Faculty Development Award.

Mentor at Research Center

Each candidate must also identify and complete arrangements with a mentor, at a preferably nearby (within reasonable commuting distance), majority or minority institution who is recognized as an accomplished, independently funded investigator in the research area proposed and who will provide guidance for the awardee's development and research plan. Plans for obtaining an intensive research experience must be developed with the mentor.

The commitment of the mentor and his/her institution to year round (i.e., summer and academic year) exposure to research must be evidenced by a letter of support from each to be included in the application. A commitment from the mentor's department chair must be included in the application.

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health Academic/teacher award (K07). Applicants will be responsible for the planning, direction, and execution of the proposed project. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No.(OASH) 90-50,000, revised October 1, 1990. Awards are non-renewable and non-transferable from one awardee to another. Funding beyond the first year of the grant is contingent on satisfactory progress during the preceding year.

Awards may be requested for a period of three to five years. Allowable costs include:

- o The salary of the applicant up to a maximum base salary of \$50,000 per year and related fringe benefits.
- o Costs for further optional preparation of the applicant in additional clinical or basic research methodologies (this aspect of the program is not to exceed the equivalent of one academic year total over the duration of the award).
- o Domestic travel expenses for the awardee to attend professional meetings, training courses, and an annual two-day awardee meeting in Bethesda, MD.
- o Partial salary support up to \$40,000 per year for one additional faculty or staff researcher as a direct participant in research-related activities or services.
- o Up to \$10,000 per year in supplies for research activities.
- o Indirect costs not to exceed a maximum of eight percent of direct costs, exclusive of tuition fees, if any.
- o The total award may not exceed \$100,000 in direct costs per year.
- o Equipment: Specialized research equipment essential to the proposed program. In accordance with PHS policy, title to such equipment will vest with the grantee institution.
- o Supplies: Consumable supplies essential to the proposed program.
- o Tuition and Fees: If essential to the awardee's individual research development program.
- o Other: Personnel, publication costs, computer costs, and other costs necessary for the research program; and

RESEARCH OBJECTIVES

This program is designed to offer support for cancer-related research to minority school faculty members at the M.D., Ph.D., or equivalent level who have the interest and capability of doing state-of-the-art research in this area.

The objective of this Program Announcement is to broaden the experience of faculty members at minority schools, to increase the pool of biomedical and behavioral investigators in cancer research, and have graduate and undergraduate students, most of whom will be minority individuals, become more cognizant of research opportunities in cancer research.

STUDY POPULATIONS

It is the NIH policy that women and minorities must be included in clinical study populations unless there is a good reason to exclude them, and the study design must seek to identify any pertinent gender or minority population differences. If appropriate, these issues must be addressed in the application.

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study populations must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

REVIEW PROCEDURE

Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to the program requirements and criteria stated in the announcement is an NCI program staff function. Applications that are judged non-responsive will be returned to the applicant. Questions concerning the relevance of proposed research may be directed to program staff as described in the INQUIRIES section.

Applications will receive technical review by an initial review group appointed by the NCI, with secondary review by the National Cancer Advisory Board.

REVIEW CRITERIA

Those applications judged to be both competitive and responsive will be reviewed for scientific and technical merit by an appropriate review group convened by the Division of Extramural Activities, NCI. The second level review by the National Cancer Advisory Board considers the special needs of the Institute and the priorities of the National Cancer Program. The following criteria will apply:

- o The overall merit of the candidate's plan for research and the development of research skills.
- o The background and potential of the proposed candidate for development into an independent biomedical investigator.
- o The candidate's commitment to a research career.
- o The ability of both the minority institution and the training center to provide facilities, resources, and opportunities necessary for the candidate's research development.
- o The commitment of the minority institution to the faculty candidate's research and development must clearly be presented in the application, including statement(s) from the sponsor and the department chair.
- o The qualifications, ability, and plans of the mentor who will provide the candidate with the guidance necessary for career development in research. Recognition of the mentor is reflected by receipt of support from national peer-reviewed funding sources.

METHOD OF APPLYING

Applications must be submitted on the grant application form PHS 398 (rev. 10/88 and 9/91) and will be accepted at the application deadlines indicated in the application kit.

Application kits are available at most institutional business and grant/contract offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301-496-7273. The title and number of this announcement must be typed on line 2 and the box checked yes.

The completed original application and six legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building Room 240
Bethesda, MD 20892**

INQUIRIES

Direct inquiries regarding programmatic issues to:

Dr. Lemuel Evans
Division of Extramural Activities
Comprehensive Minority Biomedical Program
National Cancer Institute
Building 31, Room 10A04
Bethesda, MD 20892
Telephone: (301) 496-7344
FAX: (301) 402-0062

Written and telephone inquiries concerning the objectives and scope of this Program Announcement and inquiries about whether or not specific proposed research would be responsive are encouraged and should be directed to Dr. Lemuel Evans at the above address. The Program Director welcomes the opportunity to clarify any issues or questions from potential applicants.

For information regarding budgetary/administrative issues, contact:

Ms. Carolyn Mason
Grants Management Specialist
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800, Extension 59

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.398 Cancer Research Manpower. National Institutes of Health, Public Health Service, Department of Health and Human Services authorization: Public Health Service Act, Service 413, as amended by Public Law 99-158, 42 U.S.C. 285a; Public Health Service Act, Section 487, as amended by Public Law 99-158, 42 U.S.C. 288. Federal Agency: National Institutes of Health, Public Health Service, Department of Health and Human Services authorization: Public Health Service Act, Section 301, Public Law 78-410, 42 U.S.C. 241, and Section 412, as amended by Public Law 99-158, 42 U.S.C. 285a-1. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MINORITY ONCOLOGY LEADERSHIP ACADEMIC AWARD

PA: PA-92-33

P.T. 34, FF; K.W. 0715035, 0785140, 0785035, 0785055, 0745027

National Cancer Institute

Application Receipt Dates: February 1, 1992, June 1, 1992, October 1, 1992

PURPOSE

The Comprehensive Minority Biomedical Program, Division of Extramural Activities, National Cancer Institute (NCI), invites academic health centers and other professional schools that employ, educate, or serve a preponderance of minority faculty, staff, trainees, and communities to submit applications for support of an individual to pursue leadership activities in the development of research and training programs in clinically oriented cancer research (defined as including population research; surgical, medical, or radiation oncology; cancer prevention and control; epidemiology and biostatistics; nutrition; clinical pharmacology and clinical trials; behavioral medicine; and related areas of cancer research).

The purpose of this initiative is to address underrepresentation of minority groups in research projects as investigators and subjects in research projects involving human populations. One method of addressing this problem is to broaden the experience of the faculty at minority health professional schools that serve these populations in the initiation and participation in cancer research. In doing so, the pool of clinical biomedical investigators in all aspects of cancer research will be increased, and trainees will become more cognizant of research opportunities in oncology and related disciplines. These institutions represent a unique concentration of minority faculty, trainees, and patients to address the needs outlined above.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Minority Oncology Leadership Academic Award, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402- 9325 (telephone 202-783-3238).

ELIGIBILITY AND REQUIRED ELEMENTS

Minority School

A minority health professional school is defined as a medical, dental, pharmacy, public health, or equivalent school in which students of minority ethnic groups, including African Americans, Hispanics, American Indians, and Asians or Pacific Islanders, comprise a significant proportion of the enrollments and that has a commitment to the special encouragement of minority faculty, students, and investigators.

Candidate

To be eligible, candidates must:

- o Have an appropriate clinical academic appointment at a minority health professional school at the time the award is activated. The candidate must be a citizen, a non-citizen national of the U.S., or have been lawfully admitted to the U.S. for permanent residence.
- o Have appropriate documented research experience and background in a clinical oncology specialty and/or cancer research.
- o Specify a program for enhancement of personal research skills as needed, and for the conduct of research in one or more areas cited in this announcement. Proposed research must be described in sufficient detail for reviewers to evaluate the likelihood of success of this element of the plan. All sources of support proposed for this activity must be indicated.
- o Present a program for developing or improving clinical cancer research and training capabilities at the grantee institution.
- o Commit a minimum of 60 percent total time and effort to the research and development aspects of the program.
- o Agree to report annually on the status of the program and to meet annually to exchange information with NCI staff and other awardees.
- o Specify a plan for evaluating the effect of this award on the candidate and institution.

The minority health professional school must:

- o Name and sponsor a senior or mid-level faculty member with research competence and a major career interest in oncology and/or clinical cancer research and related training programs.
- o Present plans to develop or improve cancer-related research and research training educational programs.
- o Identify and document the availability of resources (populations, patients, manpower, materials, equipment, laboratory facilities) necessary to implement the proposed program.
- o Provide the candidate with time to acquire any new skills necessary for individual professional development and for the development of the program.
- o Provide evidence of commitment from the highest levels of administration and from the sponsoring Departmental chairpersons to implement the proposed program and to coordinate it with other ongoing activities.
- o State the mechanisms planned for continued institutional support of the program in the future.

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health academic/teacher award (K07). Applicants will be responsible for the planning, direction, and execution of the proposed project. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No.(OASH) 90-50,000, revised October 1, 1990. Awards are non-renewable and non-transferable from one awardee to another. Funding beyond the first year of the grant is contingent on satisfactory progress during the preceding year.

Awards may be requested for a period of three to five years. Allowable costs include:

- o A portion of the salary of the faculty leader up to a maximum of \$50,000 per year and related fringe benefits.
- o Costs for further optional preparation of the faculty leader in additional clinical or basic research methodologies (this aspect of the program is not to exceed the equivalent of one academic year total over the duration of the award).
- o Domestic travel expenses for the awardee to attend professional meetings, training courses, and an annual two-day awardee meeting in Bethesda, MD.
- o Partial salary support up to \$40,000 per year for one additional faculty or staff researcher as a direct participant in research-related activities or services.

- o Up to \$10,000 per year in supplies for research activities.
- o Indirect costs not to exceed a maximum of eight percent of direct costs, exclusive of tuition fees, if any.
- o The total award may not exceed \$100,000 in direct costs per year.

RESEARCH OBJECTIVES

This award is aimed at encouraging and assisting a designated leader in any of the minority health professional schools to increase his/her institution's efforts in clinical cancer research in areas such as medical oncology, prevention, etiology, diagnosis, treatment, or control; and to aid in establishing a cadre of faculty and staff capable of developing new research protocols and increasing participation in intervention studies and clinical trials in these areas.

These awards offer opportunities for supporting start-up or expansion of such activities and are intended to meet needs that have not been addressed by other types of awards available from the NCI or other Federal agencies. Priority is given to those minority institutions with an interest in and commitment to expansion of clinical cancer research-related activities in local populations.

STUDY POPULATIONS

It is the NIH policy that women and minorities must be included in clinical study populations unless there is a good reason to exclude them, and the study design must seek to identify any pertinent gender or minority population differences.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or in adequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study populations must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

REVIEW PROCEDURES AND CRITERIA

Review Procedure

Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for

responsiveness to the program requirements and criteria stated in the announcement is an NCI program staff function. Applications that are judged non-responsive will be returned to the applicant. Questions concerning the relevance of proposed research Program Announcement may be directed to program staff as described in the INQUIRIES section.

Applications will receive technical review by an initial review group appointed by the NCI, with secondary review by the National Cancer Advisory Board.

Review Criteria

- o Background and potential of the named candidate as a leader in research and training activities in oncology and cancer and demonstration of effectiveness as a leader within the institution.
- o Merit of the candidate's personal plan for development and his/her plans for fostering increased research and training within the institution.
- o Scope and nature of the collaboration and commitment among participating departments and/or schools.
- o Merit of the institutional plan to strengthen research and training activities beyond the current status of activities and capacities.
- o Appropriateness and potential efficacy of the proposed use of funds to achieve the goals of the award.
- o Potential of the institution for recruitment and utilization of clinical populations and research training of clinical researchers.
- o Commitment of the institution to strengthen clinical cancer research and to support the candidate's efforts in this regard.

METHOD OF APPLYING

The research grant application form PHS 398 (rev. 10/88 and 9/91) must be used in applying to this program. These forms are available at most institutional business offices, from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892, telephone 301/496-7441, and from the NCI program director named below.

Submit a signed, typewritten original of the application, including the Checklist, and four signed, exact photocopies, in one package to DRG at the address below. The photocopies must be clear and single sided.

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At time of submission, send two (2) additional copies of the application to:

Referral Officer
Division of Extramural Activities
National Cancer Institute
Westwood Building, Room 848
5333 Westbard Avenue
Bethesda, MD 20892

The title and number of this announcement must be typed in line 2 and the box must be checked YES.

INQUIRIES

Direct inquiries regarding programmatic issues to:

Dr. Lemuel Evans
Division of Extramural Activities
Comprehensive Minority Biomedical Program
National Cancer Institute
Building 31, Room 10A04
Bethesda, MD 20892
Telephone: (301) 496-7344
FAX: (301) 402-0062

Written and telephone inquiries concerning the objectives and scope of this Program Announcement and inquiries about whether or not specific proposed research would be responsive are encouraged and should be directed to Dr. Lemuel Evans at the above address. The Program Director welcomes the opportunity to clarify any issues or questions from potential applicants.

For information regarding budgetary/administrative issues, contact:

Ms. Carolyn Mason
Grants Management Specialist
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800, Extension 59

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.398 Cancer Research Manpower. National Institutes of Health, Public Health Service, Department of Health and Human Services authorization: Public Health Service Act, Service 413, as amended by Public Law 99-158, 42 U.S.C. 285a: Public Health Service Act, Section 487, as amended by Public Law 99-158, 42 U.S.C. 288. Federal Agency: National Institutes of Health, Public Health Service, Department of Health and Human Services authorization: Public Health Service Act, Section 301, Public Law 78- 410, 42 U.S.C. 241, and Section 412, as amended by Public Law 99-158, 42 U.S.C. 285a-1.

RESEARCH FELLOWSHIPS AND CAREER DEVELOPMENT AWARDS IN ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

PA: PA-92-34

P.T. 22, 34; K.W. 0715010, 0715136, 0715185, 0715026, 0710030, 0785055

National Institute of Arthritis and Musculoskeletal and Skin Diseases

BACKGROUND

The objective of this Program Announcement is to emphasize the continuing commitment of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) to support the research development of biomedical investigators who conduct research on the basic biology, organ systems, and diseases and disorders within its mandate. The NIAMS encourages all individuals, especially members of underrepresented groups, to submit applications. The aim is to increase the expertise and development of researchers in areas relevant to the mission of the NIAMS.

SCOPE

The NIAMS encourages applications for individual fellowships and research career awards. The research emphasis or thrust of such applications must be related to the mission of the NIAMS. Major areas of interest include:

- o Arthritis and connective tissue diseases
- o Bone biology and diseases
- o Muscle biology and diseases
- o Musculoskeletal diseases and disorders
- o Skin biology and diseases
- o Musculoskeletal fitness, exercise physiology and gait analysis
- o Immunology and inflammatory processes related to diseases of connective tissue, bone, muscle, and skin
- o Epidemiology of arthritis, bone, muscle, and skin diseases
- o Structure, function and physiology of bone, muscle, skin, joints, and connective tissue
- o Metabolism of muscle, bone, and skin

MULTIDISCIPLINARY RESEARCH

Due to the complexity of the tissues and diseases, it is becoming increasingly clear that research excellence in arthritis, muscle biology, musculoskeletal disorders, and bone and skin diseases requires interdisciplinary approaches. Thus, the NIAMS encourages researchers at appropriate stages in their careers to develop additional expertise in areas such as molecular biology, cell biology, structural biology, biophysics, immunology, developmental biology, genetics, and epidemiology. Examples of multi-disciplinary approaches that are relevant to the NIAMS include, but are not limited to, the following:

- o The use of cell biology and molecular genetics to investigate the regulation of growth and proliferation of muscle, bone, and skin cells; extracellular controls (e.g., cytokines), receptors, extracellular matrix, structural function;
- o Immunology to investigate the basis of immune and autoimmune mediated diseases of muscle, bone, joints, and skin.

- o Membrane biochemistry, physiology, and molecular genetics to explore the molecular basis of defective membrane channels and ion transport in cells of muscle, bone, and skin;
- o Structural biology and human genetics to investigate the development or application of macromolecular X-ray diffraction and Nuclear Magnetic Resonance methods, computer-assisted modeling, and molecular dynamics or mechanical simulations to studies of enzyme function, molecular biology, molecular genetics, and/or biochemical genetics of hereditary diseases in model systems and humans;
- o Wide bore and whole body magnetic resonance spectroscopy and imaging of metabolic processes during rest and exercise, in normal or diseased tissue.

MECHANISMS OF SUPPORT

Several mechanisms exist that will support the professional development of individuals who can advance research in these areas. Each mechanism is tailored to a particular stage of the investigator's career. The existing mechanisms are: Individual Fellowships (F32, F33); Physician Scientist Award (PSA K11); Clinical Investigator Award (CIA K08); and Research Career Development Award (RCDA K04). Physician investigators are encouraged to use the PSA and CIA to develop expertise in basic and clinical research.

A research training or career development program for a physician-scientist should equip the individual to become an independent investigator capable of designing and executing rigorous research protocols carefully crafted to examine a hypothesis. Ideally, such investigators should be able to integrate patient-oriented and laboratory-oriented research methods to address questions related to the physiology and pathophysiology of arthritis and muscle, bone, and skin diseases and disorders.

Support mechanisms for training and research career development awards are summarized in this announcement. Detailed guidelines for each of the mechanisms may be obtained from the office of sponsored programs at most research institutions and from the Division of Research Grants, NIH, Westwood Building, Room 240, Bethesda, Maryland 20892, Phone, (301) 496-7441. Only U.S. citizens and non-citizen nationals are eligible for support under these programs.

A. INDIVIDUAL NATIONAL RESEARCH SERVICE AWARD (F32)

Individual National Research Service Awards (NRSA) are given at the postdoctoral level. The application must describe a specific research project that is guided and sponsored by a preceptor. This support is for full-time research training.

Provisions of these awards include:

- o Awards for up to 36 months of training
- o Stipends based on years of experience: range is \$18,600-32,300 per year;
- o Institutional allowance of \$3,000 per year (\$2,000 per year for fellows at NIH) to help meet expenses;
- o Support for more than 12 months requires "payback."

B. SENIOR NATIONAL RESEARCH SERVICE AWARD (F33)

Senior fellowships are designed for experienced scientists who wish to make major changes in the direction of their research career, to broaden their research capabilities, or to enlarge their command of an allied research field. Applicants for an F33 must hold a doctoral degree or equivalent and show at least seven subsequent years of relevant professional or research experience.

Provisions of the award include:

- o Awards for up to 24 months;
- o Stipend up to \$32,300 per year.

APPLICATION SUBMISSION AND REVIEW FOR FELLOWSHIP AWARDS

Application receipt dates for these two awards are January 10, May 10, and September 10. Applicants must use Fellowship Application Kit (PHS 416-1, Revised 4/89). Fellowships will be reviewed through the accelerated NIH peer review system in the Division of Research Grants. Earliest possible funding start dates will be seven to eight months after receipt dates.

Fellowship applications submitted in response to this announcement must be identified by typing PA-RESEARCH FELLOWSHIP AWARDS and PA-92-34 on Item 3 of the face page, below the title of the project.

C. PHYSICIAN SCIENTIST AWARD - (K11)

The Physician Scientist Award (PSA) is designed to encourage the newly trained clinician to develop independent research skills and experience in a fundamental science. The award is divided into two phases. During Phase I, which may last two to three years, the candidate is expected to develop independent research skills and

experience in a fundamental science. The primary sponsor must be an accomplished basic science investigator. Phase II entails intensive research activity, applying the skills learned during Phase I.

Applicants for the PSA must:

- o Hold an M.D. or equivalent clinical degree. Generally, candidates holding the Ph.D. are ineligible;
- o Have completed at least one postgraduate year of clinical training by the time of award;
- o Not have previous independent research support.

Provisions of the PSA include:

- o Five years of support, nonrenewable; durations of three or four years may be requested at the time of application;
- o Salary up to \$50,000 per year plus fringe benefits;
- o Up to \$10,000 (Phase I) and \$20,000 (Phase II) per year for research supplies, equipment, technical assistance, travel;
- o Commitment, as a minimum, of 75 percent time to PSA activities.

D. CLINICAL INVESTIGATOR AWARD - (K08)

The Clinical Investigator Award (CIA) is offered to provide the opportunity for promising clinically trained individuals with demonstrated aptitude in research to develop as independent investigators.

Applicants for the CIA must:

- o Hold an M.D. or other health professional degree;
- o Have approximately four to eight years of postdoctoral experience, both clinical and research (a minimum of two years of each) by the projected start of the award;
- o Not have been a Principal Investigator on a Public Health Service-supported research project.

Provisions of the CIA include:

- o Five years of support, nonrenewable; tenures of three or four years may be requested at time of application;
- o Salary up to \$50,000 per year plus fringe benefits;
- o Up to \$20,000 per year for research supplies, equipment, technical assistance, travel;
- o Commitment, as a minimum, of 75 percent time to the project.

E. RESEARCH CAREER DEVELOPMENT AWARD - (K04)

The Research Career Development Award (RCDA) provides salary support to enhance the research capabilities of individuals in the formative stages of their careers. Candidates who have demonstrated outstanding potential as independent investigators in health-related research, but need to be released from some of the teaching, clinical, and administrative duties assigned to junior faculty, are eligible.

Applicants for the RCDA must:

- o Hold a doctoral degree or equivalent, have usually at least five years postdoctoral research experience, and be principal investigator of a peer-reviewed research grant;
- o Describe in the application how the award will enhance development as an independent investigator;
- o Have enough independent research support for the research proposed in the RCDA application;
- o Hold a faculty appointment.

Provisions of the RCDA include:

- o Five years of support, nonrenewable;
- o Salary up to \$50,000 per year plus fringe benefits. No funds are available under this award for research expenses. These expenses are expected to be included in the independent research support described above.
- o Commitment of at least 80 percent time to research. The remaining time (up to 20 percent) must be spent on research-related activities that will enhance research career development.

RCDA applications may be submitted concurrently with a traditional research grant application but may not be submitted concurrently with other development awards such as PSA, CIA, or First Independent Research Support and Transition (FIRST) Award.

APPLICATION SUBMISSION AND REVIEW FOR THE K AWARDS

Application receipt dates for all career development awards (K series) are February 1, June 1, and October 1. The PSA and CIA applications will be reviewed by an appropriate review committee within a funding Institute. RCDA applications will be reviewed by an initial review group in the Division of Research Grants. Earliest possible funding dates are approximately 10 months after the receipt dates. Use application form PHS 398, Rev. 10/88 and 9/91, with special instructions for the PSA, CIA, and RCDA ("The K Awards," October 1991) available from the Office of Grants Inquiries.

Applications submitted in response to this announcement must be identified by typing PA-RESEARCH CAREER AWARDS and PA-92-34 on line 2 of the face page, below the title of the project.

The typed original application and six signed exact single-sided photocopies must be submitted or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may identify the GCRC as a resource for conducting the proposed activity. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator must be included with the application.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority populations groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' population, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

INQUIRIES

For further information about these awards, contact:

Richard W. Lynn, Ph.D.
Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 403
Bethesda, MD 20892
Telephone: (301) 496-7495

For administrative and fiscal matters, contact:

Diane Watson
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 407-A
Bethesda, MD 20892
Telephone: (301) 496-7495

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and Part 66 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

TRAINING AND DEVELOPMENT: NURSING AND BIOLOGY INTERFACE

PA: PA-92-35

P.T. 44; K.W. 0785130, 1002000, 0785035

National Center for Nursing Research

PURPOSE

This program announcement identifies specific research training and career development support mechanisms for the purpose of integrating biological theory, measurements, and techniques with nursing research and practice. Applicants must focus on basic biological investigations pertaining to nursing clinical questions, technological and/or clinical protocols, and nursing research based on biobehavioral theories, measurements, and techniques.

ELIGIBILITY REQUIREMENTS

All policies and requirements that govern the grant programs of the Public Health Service apply. Applicants must meet the respective criteria for the Individual National Research Service Awards (NRSA) or the Clinical Investigator and Academic Investigator Awards as stipulated by the National Center for Nursing Research (NCNR) and PHS policy. Applications from minority individuals and women are encouraged.

MECHANISMS OF SUPPORT

The mechanisms of support for this program will be the Individual Predoctoral NRSA fellowship (F31); the Individual Postdoctoral NRSA fellowship (F32); the NRSA Senior Fellowship (F33); training positions on existing Institutional NRSA research training grants (T32s) funded by other NIH components; the NCNR Academic Investigator Award (K07); and the NCNR Clinical Investigator Award (K08). The regulations that govern the research training and career development programs of the Public Health Service and NCNR will prevail.

RESEARCH OBJECTIVES

An important focus of nursing research in the improvement of patient care is the interaction of biological and behavioral factors associated with acute and chronic illness and health promotion and disease prevention. NCNR believes that in order to explore this biobehavioral interface, training and career development resources must be focused on areas of biological science that underlie nursing practice.

Recognizing the rapid changes that are taking place in the biomedical sciences and the effect these changes will have on nursing research and practice, the biological content of the NCNR portfolio was analyzed. Nurse physiologists comprising the Biological Task Force recommended strategies to integrate nursing research with state-of-the-art biological science. These recommendations were approved by the National Advisory Council for Nursing Research. A long-range plan for implementing the Task Force's recommendations includes research initiatives to increase the interface of biological sciences with nursing research as a basis for clinical practice and education. The first step in this plan is to increase opportunities for research training and career development in the biological sciences.

The specific objectives of NCNR research training and career development in the biological sciences are: 1) to develop a cadre of nurse scientists with research training at the predoctoral and postdoctoral level in the biological science; and 2) to enhance the knowledge base of doctorally prepared mid-career nurses whose research involves biological science. Examples of biological science disciplines are physiology, pharmacology, anatomy, biochemistry, molecular biology, genetics, pathology, and/or immunology. The overall goal of this training

initiative is to increase the number of nurse researchers in the biological sciences prepared to explore the biological underpinnings of nursing practice and research. To accomplish this goal, it is mandatory for each applicant to include a nurse scientist as a co-sponsor when the biological scientist does not have a nursing degree.

Opportunities for nurse scientists to collaborate with biological scientists from other disciplines are encouraged. Training and career development programs should provide opportunities for nurses to conduct supervised clinical and basic biological research with the primary objective of extending their research skills and knowledge to the interface between nursing and one of the biological disciplines. The academic, clinical, and laboratory environment should facilitate growth and development for promising students, new research scientists, and mid-career scientists. Examples of important training opportunities include ongoing interactive departmental seminars, a faculty well published in refereed journals, and an interactive, interdisciplinary research team with multiple funding sources including an established sponsor with a funded program of research.

Extraordinary advances in scientific knowledge have confirmed the essential unity of basic biological and behavioral research. Behavioral research, mental health research, and psychosocial research can no longer be considered as separate from genetics, molecular biology, and immunology. For example, information processing by the brain is a major factor in behavioral disorders and stress reactions. The autonomic nervous system can be modified through cognitive techniques such as biofeedback and relaxation. New fields such as psychoneuroimmunology focus on the integral relationships and reciprocal interactions of the immune, nervous, and endocrine systems and other systems of the body that affect health and well-being.

o Targeted Predoctoral (F31) and Postdoctoral (F32) Fellowships and Targeted Senior Fellows (F33)

The F31, F32, and F33 biological science fellowships will focus on biomedical science development, advanced clinical science development, and supervised research training experience. Applicants must integrate an area of biological theory with a relevant nursing problem. For example, postdoctoral studies in biochemistry targeting gluconeogenesis would be relevant to the nursing problem of caring for critically injured multiple trauma patients who experience severe organ failure. It is necessary that sponsor(s) be either a biological nurse scientist or a biological scientist with a nurse scientist as co-sponsor.

The F31 predoctoral biological science fellowship is designed to provide predoctoral nurses with supervised clinical and/or basic biological research training leading to the Ph.D. Applicants must be registered nurses.

The F32 postdoctoral biological science fellowship, a priority of the NCNR, is designed to provide postdoctoral research training to nurse scientists to refine their research interests, initiate independent research programs, and to gain depth of knowledge in their clinical and/or basic biological research area. In order to prepare scientists to explore the biological underpinnings of nursing practice and research, applicants must integrate biological science with a nursing problem or a clinical practice issue. Priority status will be given to nurses with doctorates who submit a successful postdoctoral NRSA application enabling continued training without a time break. To ensure maximum growth and development as a research scientist and to increase the integration of new theories and ideas, postdoctoral fellows are advised to choose universities or departments other than the site of their doctoral training.

The F33 senior biological science fellowship award is designed to provide advanced training for experienced nurse scientists (with at least seven years of relevant research experience beyond the doctoral level). These awards will enable nurse scientists to take time from regular professional responsibilities and to make major changes in the direction of their research careers or to broaden their scientific background by acquiring new research capabilities. This award is directed at nurse researchers well prepared in biological science who desire to learn new methodologies and techniques. For example, a nurse scientist might combine sabbatical time with F33 funding to investigate the biobehavioral link between depression and lymphocyte function in chronically ill patients.

Meritorious applications that are responsive to the objectives of this program announcement will be given high program relevance.

o Training Positions on Existing Institutional Training Grants (T32) Currently Funded by Other NIH Institutes, Centers and Divisions

Existing institutional training grants within NIH may provide nurse scientists predoctoral and postdoctoral opportunities for biomedical research training. These traineeships are designed to place qualified individuals in biomedical science environments. Candidates must have co-sponsors with nurse scientists when mentorship with biological nurse scientists is not possible. Nurse candidates are advised to contact the T32 Principal Investigator directly to discuss potential predoctoral or postdoctoral opportunities.

o Targeted Mid-Career Academic (K07) and Clinical Investigator (K08) Award

The purpose of these targeted awards is two-fold: (1) to teach biological measurements and techniques to accomplished nurse researchers who have little formal training in biological science but conduct research in a biobehavioral framework; and (2) to teach accomplished nurse biological researchers state-of-the-science biological research, especially cutting edge biological technology and bioinstrumentation applicable to nursing research and practice. To ensure a commitment to nursing research and in order to achieve an effective interface between the biological and nursing foci, the candidate must have a nurse scientist as a co-sponsor when the basic biological scientist or clinically trained scientist is not a nurse. The objectives of these mechanisms are to interface biological science with nursing research, with a focus on clinical practice. These

targeted awards are designed to provide mid-career development in molecular biology, physiology, anatomy, biochemistry, genetics, pathology, pharmacology, and immunology.

The NCNR K07 mechanism allows promising nursing faculty to take time from administrative and teaching duties to establish research programs and mature into independent investigators. The candidate must be sponsored by a basic biological scientist who is recognized as an established investigator in the research area proposed, who has had experience in training independent investigators, and who will provide the mentorship required in the respective dimension of biological science.

The NCNR K08 mechanism enables promising clinically trained individuals with a doctoral degree to become independent scientists under a sponsor. Applicants from institutions that have a GCRC funded by the NIH National Center for Research Resources (NCRR) may wish to identify the GCRC as a resource for conducting the proposed research. A letter of agreement from either the GCRC program director or Principal Investigator of the NIH-supported program must be included with the application.

NCNR guidelines for the standard K07 and K08 mechanisms have been published in the NIH Guide for Grants and Contracts, Volume 20, No. 20, May 24, 1991.

In addition to the established K07 and K08 mechanisms, the usual guidelines of four to eight years beyond the doctorate may be waived for nurse scientists who have been Principal Investigators in the past or may be a current Principal Investigator of a research grant (R01). If a candidate exceeds the eight-year limit stipulated in the guidelines, an explanation of special qualifying circumstances must be provided in the application.

Meritorious applications that are responsive to the objectives of this program announcement will be given high program relevance.

STUDY POPULATIONS

It is the NIH policy that women and minorities must be included in clinical study populations. The study design must seek to identify any pertinent gender or minority population differences.

REVIEW PROCEDURES

Applications in response to this announcement will be reviewed in competition with other applications and in accord with the customary NIH peer review procedures and criteria. Applications will be reviewed for scientific and technical merit by an initial review group. Second level review for the Career Development (K07, K08) awards will be conducted by an appropriate national advisory council. Second level review of individual fellowship (F31, F32, F33, T32) applications will be conducted by an appropriate Executive Review Group.

APPLICATION PROCEDURES

Applicants for individual NRSA fellowships must use form PHS 416-1 (rev. 4/89). Career Development Award applicants must use PHS 398 (rev. 10/88). In order to expedite processing of the applications indicate that this is in response to this program announcement on line 3 of the PHS 416-1 face page; and line 2 of the PHS 398 face page. Applications must be submitted to the Division of Research Grants in accordance with the usual receipt dates. The mailing address is:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892

INQUIRIES

Written and telephone inquiries concerning this program announcement are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Direct inquiries regarding programmatic issues to:

Hilary D. Sigmon, Ph.D., R.N.
Nurse Scientist Administrator
National Center for Nursing Research
Building 31, Room 5B03
Bethesda, MD 20892
Telephone: (301) 496-0523

Direct inquiries regarding fiscal matters to:

Ms. Sally Nichols
Grants Management Officer
National Center for Nursing Research
Building 31, Room 5B06
Bethesda, MD 20892
Telephone: (301) 496-0237

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.361, Nursing Research. Awards are made under the authority of the PHS Act, Sections, 301, 483, 484, 485, and 487 as amended by Public Law 99-158 and 97-219. Awards are administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21, No. 3, Part I of II
January 24, 1992

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RESEARCH SUPPLEMENTS FOR UNDERREPRESENTED MINORITIES

NIH GUIDE, Vol. 21, No. 3, Part I of II, January 24, 1992

P.T. 34, 44, FF; K.W. 0720005, 0710030

National Institutes of Health

BACKGROUND

During 1987 and 1988, the Director of the National Institutes of Health (NIH) and the Advisory Committee to the Director (ACD) held a series of regional meetings throughout the United States. At these meetings, testimony was presented by concerned individuals and organizations regarding the underrepresentation of minorities in biomedical and behavioral research. Although the NIH currently provides opportunities for minorities through the traditional research grant programs and through special initiatives supported by various components of the NIH (see APPENDIX for listing), the testimony indicated that efforts of the NIH should be increased. In addition, the NIH recognizes the need to increase the number of underrepresented minority scientists participating in biomedical and behavioral research as a means of addressing a potential research labor shortage in the twenty-first century.

In response to these concerns, the NIH is emphasizing the use of administrative supplements to attract minorities into biomedical and behavioral research. The mechanisms described in this announcement have been endorsed by all the awarding components of the NIH and are designed to provide support for research experiences at grantee institutions for minorities throughout the continuum from the high school to the faculty level. The funding of these programs will be in addition to existing programs for minority individuals and institutions described in the APPENDIX.

The NIH hereby notifies all Principal Investigators holding NIH research grants that funds are available for administrative supplements to existing grants for the support and recruitment of underrepresented minority scientists and students. The aim of these supplements is to attract and encourage minority individuals to enter and pursue biomedical and behavioral research careers in areas within the missions of all the awarding components of the NIH by providing supplemental funds to certain ongoing research grants (see the Eligibility section under GENERAL PROVISIONS).

For the purpose of these announcements, underrepresented minority students and investigators are defined as individuals belonging to a particular ethnic or racial group that has been determined by the grantee institution to be underrepresented in biomedical or behavioral research. Awards will be limited to citizens and non-citizen nationals of the United States and to individuals who have been lawfully admitted for permanent residence (i.e., in possession of an Alien Registration Receipt Card) at the time of application. In awarding supplements, the NIH will give priority to projects involving Black, Hispanic, Native American, and Pacific Islander and other ethnic or racial group members who have been found to be underrepresented in biomedical or behavioral research nationally.

The NIH anticipates that by providing scientific opportunities, such as those listed below, the number of minorities entering and remaining in biomedical research careers will increase.

- o Research Supplements for Minority High School Students will support minority high school students who have expressed an interest in biomedical or behavioral sciences.
- o Research Supplements for Minority Undergraduate Students will support minority undergraduate students who have demonstrated an interest in biomedical or behavioral sciences and wish to continue on to graduate level training in these areas.
- o Research Supplements for Minority Graduate Research Assistants will provide support to assist minority predoctoral students who wish to develop research capabilities in the biomedical and behavioral sciences.
- o Research Supplements for Minority Individuals in Postdoctoral Training will provide support for minority individuals to participate as postdoctoral researchers in ongoing research projects in preparation for independent careers in biomedical or behavioral research.
- o Research Supplements for Minority Investigators will provide short- and long-term opportunities for minority staff and faculty to participate in ongoing research projects while further developing their own independent research potential.

GENERAL PROVISIONS

In all cases, the proposed research experience must be an integral part of the approved ongoing research of the parent grant. As part of this research experience, the minority individual must be given the opportunity to interact with individuals on the parent grant, to contribute intellectually to the research, and to enhance his/her research skills and knowledge regarding the particular area of biomedical science. Furthermore, the Principal Investigator must demonstrate a willingness and understanding that the purpose of the award is to enhance the research capability of the minority student or faculty member, and that the research experience is intended to provide opportunities for minority individuals to develop as independent, competitive research investigators. Supplemental awards will be consistent with the goal of strengthening the existing research program and with the overall programmatic balance and priorities of the funding component of the NIH. Awards will be made according to the policies and provisions stated in this announcement.

Applicants are encouraged to contact the NIH institute staff identified in the INQUIRIES section prior to submission to obtain specific information about application characteristics and submission requirements. It is also recognized that individual circumstances vary, and for unusual situations, NIH program administrators should be consulted for a determination of eligibility.

ELIGIBILITY

Principal Investigators at domestic institutions who hold an active Research Centers in Minority Institutions Award (G12), Research Project (R01), Cooperative Clinical Research (R10), Research Demonstration and Dissemination Projects (R18), U.S. - Japan Cooperative Medical Science Program (R22), Resource-Related Research Projects (R24), Outstanding Investigator Grants (R35), Method to Extend Research in Time (MERIT) (R37), Research Program Projects (P01), Exploratory Grants (P20), Center Core Grants (P30), Animal (Mammalian and Non-mammalian) Model, and Animal and Biological Materials Resource Grants (P40), Biotechnology Resource Grant Program (P41), Specialized Center (P50), Comprehensive Center (P60), Cooperative Agreement (U01) grant are eligible to submit a request for an administrative supplement to the awarding component of the parent grant for any of the supplemental programs offered here. Principal Investigators holding an active First Independent Research Support and Transition (FIRST) Award (R29) also may apply for a supplement under this program, but only when the minority candidate is a high school, undergraduate, or graduate student. Minority supplements to R29 awards may provide support above the established dollar limits on these awards.

In all cases, the parent grant must have support remaining for a reasonable period at the time of a supplemental award. Principal Investigators are encouraged to submit an application no later than three months before the anniversary date of the last two years remaining on the parent grant.

The purpose of the request will be to support an underrepresented minority high school student, undergraduate student, graduate research assistant, individual in postdoctoral training, or a staff or faculty member to participate in an ongoing research project. Specific eligibility requirements relative to each type of award are set forth in the description of the individual supplement programs (below).

Usually, each parent grant would support only one minority supplement. Appointment of more than one individual to a single grant will be considered depending on the nature of the parent grant, the circumstances of the request, and the program balance of the awarding NIH component. Minority individuals may receive support from only one of these supplement programs at a time, but may be supported by more than one minority supplement during the development of their research careers. Opportunities for support under the supplement programs are not transferable to another individual.

The minority supplement programs have been designed to attract underrepresented minority individuals into research careers and are not intended to provide an alternative means of supporting minority individuals who already receive support from a research grant or other PHS funding mechanism. If the Principal Investigator wishes to transfer a minority individual to supplemental support from an existing PHS supported position, the reason for the transfer must be clearly documented along with efforts to fill the vacated position with another minority individual. Individuals may not be transferred to a minority supplement simply to increase the availability of funds of the parent grant for other uses such as supplies and travel. Minority graduate students or individuals in postdoctoral training who are supported by a National Research Service Award (NRSA) Institutional research training grant may not be transferred to supplemental support prior to the completion of their appointed period of training.

APPLICATION PROCEDURES

A request for a supplement may be submitted at any time. IN MAKING REQUESTS, THE GRANTEE INSTITUTION, ON BEHALF OF THE PRINCIPAL INVESTIGATOR OF THE PARENT GRANT AND IN COOPERATION WITH THE MINORITY INDIVIDUAL, MUST SUBMIT THE REQUEST FOR SUPPLEMENTAL FUNDS DIRECTLY TO THE AWARDING COMPONENT THAT SUPPORTS THE PARENT GRANT. The request is NOT to be submitted to the NIH Division of Research Grants. Principal Investigators are encouraged to obtain the address for submission from the NIH program administrator on the parent grant.

The request for a supplemental award must include the following:

- o a completed face page (with appropriate signatures) from grant application form PHS 398. Include the title and grant number of the parent grant and the type of supplement being requested on line 1;
- o a brief three to four page description, prepared by the Principal Investigator of the parent grant, that includes:
 - (a) a summary or abstract of the funded grant or project,
 - (b) a description of the research experience proposed for the minority individual,
 - (c) how the experience will expand and foster the independent research capabilities of the minority individual, and
 - (d) how the proposed experience relates to the specific research goals and objectives of the parent grant;
- o a signed statement from the minority individual outlining his/her research objectives and career goals;
- o the social security number and biographical sketch of the minority individual that includes evidence of scientific achievement or interest;

- o a signed statement from the Principal Investigator establishing the eligibility of the minority individual for support under this program including information on ethnicity, citizenship, and a description of any previous PHS research grant support the minority individual has received;
- o a proposed budget entered on budget pages from grant application form PHS 398, related to the percent effort (where appropriate) for the research experience of the minority individual during the first and future years. If the initial budget period requested is less than 12 months, the budget must be prorated accordingly;
- o documentation, if applicable, that the proposed research experience was approved by the Institutional Animal Care and Use Committee (IACUC) or human subjects Institutional Review Board (IRB) of the grantee institution;
- o a copy of the most recent official transcript if the minority candidate is a high school, undergraduate or graduate student;
- o if the minority individual is a student at another institution, the application also must include an appropriately signed letter from a responsible official at the institution of matriculation indicating that participation at the stated level of effort is approved and will not detract from or interfere with his/her course of studies;
- o if any of the research is to be conducted at a site other than the grantee institution, an appropriately signed letter from the institution where the research is to be conducted must also be submitted.

The request must be signed by the minority individual, the Principal Investigator, and the appropriate institutional business official.

REVIEW CRITERIA

The staff of the particular awarding component will review requests for supplements using the following general criteria:

- o the qualifications of the minority individual including career goals, prior research training, research potential, and any relevant experience;
- o the plan for the proposed research experience in the supplemental request and its relationship to the parent grant;
- o evidence from the Principal Investigator that the experience will enhance the research potential, knowledge, and/or skills of the minority individual;
- o evidence from the Principal Investigator that the activities of the minority individual are an integral part of the project.
- o evidence of educational achievement and interest in science if the minority candidate is a student.

FUNDING

The decision to fund a supplement will take six to eight weeks from the time all the necessary information is received. Applicants for summer-only research appointments must submit early enough to ensure that funding is in place by the time the summer experience is scheduled to begin. In most cases during the first budget period, funds will be provided as an administrative supplement to the parent grant. In subsequent years, continued funding for the supplement is contingent on funding of the parent grant and cannot extend beyond the current competitive segment of the parent grant.

The continuation of support for the minority individual in the remaining years of the competitive segment of the grant will depend upon satisfactory review by the NIH awarding component of progress for both the parent grant and the supplemental project, the research proposed for the next budget period, and the appropriateness of the proposed budget to the proposed effort.

In non-competing continuation applications, the progress report for the minority supplement must be clearly delineated from the progress report for the parent grant. The progress report in both non-competing and competing applications must include information about the research activities supported by the supplement even if support for future years is not requested. In future competing applications, funds for continuation of support for the minority individual must be requested in the parent grant application and may not be requested as a research supplement for that individual.

DESCRIPTIONS OF THE INDIVIDUAL RESEARCH SUPPLEMENT PROGRAMS

1. RESEARCH SUPPLEMENTS FOR UNDERREPRESENTED MINORITY HIGH SCHOOL STUDENTS

DESCRIPTION

The purpose of this program is to provide minority high school students with an opportunity to attain a meaningful experience in various aspects of health-related research to stimulate their interest in careers in biomedical or behavioral science. Principal Investigators may identify appropriate high school students through the local program director for the Minority High School Student Research Apprentice Program (MHSSRAP). (See Appendix for a description of MHSSRAP.) The Principal Investigator should coordinate the selection of minority

high school students and the research experience planned under the supplement with the program director of the MHSSRAP grant. Alternatively, if the Principal Investigator is not located at an institution that administers a MHSSRAP program, the grantee institution, in conjunction with local high schools, may attempt to pair high school students with funded Principal Investigators. Information about funded MHSSRAP programs near the Principal Investigator's institution may be obtained from the National Center for Research Resources. (See the INQUIRIES section at the end of this announcement.)

ELIGIBILITY

Any minority high school student who is currently enrolled in good standing at his/her high school and interested in biomedical or behavioral research is encouraged to participate in this program.

PROVISIONS

This supplement may not exceed \$2,000 per student, including supplies, for a summer experience. A part-time experience during the regular school year would be reimbursed at the same rate. This is the same level of support provided under the MHSSRAP program. Equipment may not be purchased using these funds. Students are expected to devote sufficient effort to the research project and related activities during the period of support to gain insight into the process of scientific discovery. Support should be for a minimum of three months during any one year, which may include a mixture of full-time summer experience and part-time experience during the school year. Principal Investigators are encouraged to seek minority high school students who will devote at least two years to this program (i.e., equivalent to two three-month, full-time, periods). Exceptions to the latter will be considered, depending on the circumstances of the applicant, the parent grant, and the specific request.

See the GENERAL PROVISIONS section for information about application procedures, review criteria, and funding.

2. RESEARCH SUPPLEMENTS FOR UNDERREPRESENTED MINORITY UNDERGRADUATE STUDENTS

DESCRIPTION

This supplemental program provides an opportunity for any minority undergraduate student interested in biomedical or behavioral research to participate in a research project at a research institution during the summer months or during the school year. This experience will be separate from any requirement of the regular academic program.

The success of this program is dependent on the ability of the Principal Investigator to identify appropriate students. A number of procedures may be used to match investigators holding research grants to appropriate minority college students:

- o the Principal Investigator may identify a student and initiate the request for the supplement;
- o the institution may make the pairing and request the supplement;
- o the student may contact a grantee institution or the Principal Investigator and request a summer research experience;
- o finally, the NIH can provide lists of participants in NIH programs that provide support for minority undergraduate students (such as the Minority Access to Research Careers and the Minority Biomedical Research Support Program) to help the Principal Investigator identify suitable candidates.

ELIGIBILITY

The student may be affiliated with either the applicant institution or any other academic institution. Any undergraduate minority student interested in biomedical or behavioral research is encouraged to participate in this program.

PROVISIONS

This supplement is not to exceed \$6.00 per hour for salary plus \$125 per month for supplies and travel. Equipment may not be purchased from these funds. Students are expected to devote an equivalent of at least three months full-time effort to the research project and related activities in any one year and in most cases the period of support for any individual should last at least two years. Exceptions to these requirements will be considered, depending on the circumstances of the applicant, the parent grant, and the specific request.

See the GENERAL PROVISIONS section (above) for information about application procedures, review criteria, and funding.

3. RESEARCH SUPPLEMENTS FOR UNDERREPRESENTED MINORITY GRADUATE RESEARCH ASSISTANTS

DESCRIPTION

The objective of this program is to offer additional encouragement to minority graduate students already in biomedical and behavioral sciences and provide an opportunity to develop their research capabilities further.

ELIGIBILITY

Any minority graduate student who is enrolled in a masters or a doctoral degree program in one of the biomedical or behavioral sciences is eligible for consideration. Students enrolled in a masters degree program in nursing sciences are also eligible.

PROVISIONS

The NIH will provide salary support in addition to other necessary expenses, such as supplies and travel, to enable the individual to participate as a graduate research assistant in funded research projects. The requested salary must be in accordance with the salary structure of the grantee institution and consistent with the level of effort. Funds may not be used to purchase equipment.

See the GENERAL PROVISIONS section (above) for information about application procedures, review criteria, and funding.

4. RESEARCH SUPPLEMENTS FOR UNDERREPRESENTED MINORITY INDIVIDUALS IN POSTDOCTORAL TRAINING

DESCRIPTION

These supplements provide support for minority individuals in the postdoctoral phase of training to participate in ongoing research projects to assist the development into an independent biomedical or behavioral researcher.

ELIGIBILITY

The minority individual in postdoctoral training may be affiliated with either the applicant institution or any other institution. Only under extraordinary circumstances, that must be well justified in the application, would it be acceptable for the postdoctoral candidate to work with his/her former predoctoral mentor.

PROVISIONS

The NIH will provide support for a salary in addition to other necessary expenses, such as travel and supplies, to enable the minority individual to participate as a postdoctoral research assistant or associate on the funded research project. The requested salary must be in accordance with the salary structure of the grantee institution and consistent with the level of effort. Support may not be used to purchase equipment.

See the GENERAL PROVISIONS section (above) for application procedures, review criteria, and funding.

5. RESEARCH SUPPLEMENTS FOR UNDERREPRESENTED MINORITY INVESTIGATORS

DESCRIPTION

These supplements provide either short- or long-term research support for minority staff or faculty members to enhance their research skills leading to an independent research career.

Short-term Minority Investigator Research Supplement. This supplement provides short-term support for minority staff or faculty members to conduct full-time research for three to five months each year during the summer or another portion of the academic year, over a maximum period of four years.

Long-term Minority Investigator Research Supplement. This supplement provides long-term research support for minority staff or faculty members to conduct research in the biomedical or behavioral sciences. Support is provided for up to 4 years at a minimum of 30 percent effort during each 12-month period.

ELIGIBILITY

The minority investigator may be affiliated with the applicant institution or any other institution. The investigator must have a doctoral degree, be beyond the level of a research trainee and be a member of the staff or faculty with at least one year of postdoctoral experience. A minority individual who has previously received support from the Minority Biomedical Research Support (MBRS), Minority Access to Research Careers (MARC), small grants (R03), or Academic Research Enhancement Awards (AREA) programs is eligible for these supplements. On the other hand, an individual who has received previous funding from NIH as an independent Principal Investigator on an individual research grant (e.g., R01, R29), or as the project leader on a component of a program project or center grant (e.g., P01, P50), or as a Principal Investigator on an individual research career award (e.g., K04, K08, K11) is NOT eligible.

PROVISIONS

The minority investigator supplemental award is for a maximum of \$50,000 in direct costs per year. A maximum of \$40,000 may be requested for salary and fringe benefits; additional funds up to \$10,000 may be requested for supplies and travel. Equipment may not be purchased except in unusual circumstances and not without prior approval of the NIH awarding component. The maximum period of support for any investigator is four years.

The amount of salary requested must be consistent with the policies of the parent grantee institution (and, if applicable, the minority investigator's employing institution) and must be related to the percent effort of the minority investigator.

See the GENERAL PROVISIONS section (above) for application procedures, review criteria, and funding.

INQUIRIES

Principal Investigators interested in participating in these programs are encouraged to contact NIH staff administering the parent grant. For general information about the Research Supplements for Underrepresented Minorities, contact the following staff person in the appropriate awarding component:

National Institute on Aging
Deputy Associate Director, Office of Extramural Affairs
Building 31, Room 5C02
Bethesda, MD 20892
Telephone: (301) 496-9322

National Institute of Allergy and Infectious Diseases
Assistant Director, Division of Extramural Activities
Westwood Building, Room 705
Bethesda, MD 20892
Telephone: (301) 402-0159

National Institute of Arthritis and Musculoskeletal and Skin Diseases
Director, Extramural Program
Building 31, Room 4C32
Bethesda, MD 20892
Telephone: (301) 496-0802

National Institute of Child Health and Human Development
Special Assistant to the Deputy Director
Building 31, Room 2A03
Bethesda, MD 20892
Telephone: (301) 496-0104

National Institute on Deafness and Other Communication Disorders
Director, Division of Extramural Activities
6120 Executive Blvd., EPS-400B
Rockville, MD 20892
Telephone: (301) 496-8693

National Institute of Dental Research
Director, Extramural Program
Westwood Building, Room 503
Bethesda, MD 20892
Telephone: (301) 496-7723

National Institute of Diabetes and Digestive and Kidney Diseases
Assistant Director for Grants and Contracts
Division of Extramural Activities
Westwood Building, Room 657
Bethesda, MD 20892
Telephone: (301) 496-7793

National Institute of Environmental Health Sciences
Director, Division of Extramural Research and Training
Building 3, Room 301A
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-7723

National Institute of General Medical Sciences

o For general information contact:

Assistant Director, Referral and Liaison
Westwood Building, Room 925
Bethesda, MD 20892
Telephone: (301) 402-0593

o For information on procedures for initiating an application for a supplement, contact the program administrator or:

Deputy Associate Director, Office of Program Activities
Westwood Building, Room 938
Bethesda, MD 20892
Telephone: (301) 496-7063

National Institute of Neurological Disorders and Stroke

Deputy Director, Division of Extramural Activities
Federal Building, Room 1016
Bethesda, MD 20892
Telephone: (301) 496-4188

National Cancer Institute
Director, Division of Extramural Activities,
Building 31, Room 10A03
Bethesda, MD 20892
Telephone: (301) 496-5147

National Eye Institute
Research Training and Resources Officer
Building 31, Room 6A49
Bethesda, MD 20892
Telephone: (301) 496-5983

National Heart, Lung and Blood Institute
Director, Division of Extramural Affairs
Westwood Building, Room 7A17B
Bethesda, MD 20892
Telephone: (301) 496-7416

National Center for Nursing Research
Director, Extramural Programs
Building 31, Room 5B03
Bethesda, MD 20892
Telephone: (301) 496-0523

National Library of Medicine
Acting Associate Director, Division of Extramural Programs
Building 38A, 5N505
Bethesda, MD 20892
Telephone: (301) 496-4621

National Center for Research Resources
Acting Deputy Director for Extramural Research Resources
Building 12A, Room 4011
Bethesda, MD 20892
Telephone: (301) 496-6023

National Center for Human Genome Research
Chief Research Grants Branch
Building 38A, Room 612
Bethesda, MD 20892
Telephone: (301) 496-7531

APPENDIX

ADDITIONAL NIH SUPPORT FOR MINORITY INVESTIGATORS

In addition to the Research Supplements for Underrepresented Minorities in Biomedical Research, the NIH supports minority investigators through a variety of other mechanisms. Below is a list of these programs. For additional information about individual programs, contact the appropriate NIH staff person listed above.

Research Related Grant Programs

The Minority Biomedical Research Support (MBRS) Program provides research grants to colleges, universities, health professional schools with substantial minority enrollments, and tribally controlled institutions on Indian reservations. These grants support research by faculty members, strengthen the institution's biomedical research capabilities, and provide opportunities for students to work as part of a research team. The MBRS Program is administered by the National Institute of General Medical Sciences.

The MBRS Program provides support through two major grant mechanisms. The Traditional MBRS Program primarily supports faculty research projects but also places emphasis on promoting the involvement of undergraduate and graduate students. The MBRS Program for Undergraduate Colleges supports enrichment activities, pilot research projects, and regular research projects at undergraduate institutions. Enrichment activities, which are a required component of this type of grant, include workshops, attendance at scientific meetings, and summer research experiences for faculty and students at off-campus laboratories.

The Research Centers in Minority Institutions (RCMI) Program provides grant support to predominantly minority institutions that offer the doctoral degree in the health sciences. RCMI funds are used to hire additional research faculty in the biomedical and behavioral sciences, support training in specialized analytical methods, upgrade facilities, and purchase advanced scientific instrumentation. This program is administered by the National Center for Research Resources.

The National Cancer Institute Cancer Education Programs supports networks consisting of Black churches and historically Black colleges and universities as part of its overall program. This initiative is targeted toward traditionally underserved populations that are at high risk for certain malignancies.

The Minority Travel Award Program of the National Institute of Arthritis and Musculoskeletal and Skin Diseases and the National Institute of Diabetes and Digestive and Kidney Diseases provides travel funds for minority students and faculty members from minority institutions for attendance at national scientific meetings.

The Resource Grant Program supports the development of health science libraries at minority institutions. In addition, minority institutions benefit from the Regional Medical Library Program that provides services and conducts activities relative to the retrieval and utilization of health information. These programs are supported by the National Library of Medicine.

Career Development Programs

The Junior Research Investigator Enhancement Award supports minority scientists from member institutions of the Association of Minority Health Professional Schools who are pursuing or plan to pursue careers in research related to heart, lung or blood diseases. This program is supported by the National Heart, Lung, and Blood Institute.

The Minority Clinical Associate Physicians (MCAP) Program provides up to three years of support to minority physicians and dentists to promote career development as independent clinical investigators, under the direction of senior clinical scientists who act as sponsors. A request for MCAP support is made through a supplemental grant application from a funded General Clinical Research Center of the National Center for Research Resources.

The Minority Investigator Research Enhancement Award is administered by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and provides support to faculty members from minority institutions for collaboration with Principal Investigators on currently funded NIAMS or NIDDK research grants.

The Minority Satellite Supplement supports minority clinical faculty to contribute to the research effort of the National Cancer Institute clinical trials research groups.

The Minority School Faculty Development Award supports faculty investigators at minority schools in areas relevant to cardiovascular, pulmonary, and blood disease research. This program is supported by the National Heart, Lung, and Blood Institute.

Research Training and Fellowship Programs

The Intramural Summer Student Employment Program supports high school, undergraduate, and graduate students, and college faculty members to conduct research in the biomedical sciences at the NIH. This program is supported by the NIAMS.

The Minority Access to Research Careers (MARC) Program awards research training grants and fellowships (see next four items) that help increase the number and capabilities of minority biomedical research scientists and strengthen science curricula and research opportunities at institutions with substantial minority enrollments. These programs are administered by the National Institute of General Medical Sciences.

- o The MARC Honors Undergraduate Research Training Grant assists minority institutions to develop strong undergraduate science curricula, stimulate an interest in biomedical research among undergraduate students, and increase the number of well-prepared minority students who can compete successfully for entry into graduate programs leading to the Ph.D. degree in the biomedical sciences. Under this program, minority institutions receive support to provide honors students with science courses, research training, and summer research experience outside the home institution.
- o The MARC Predoctoral Fellowship provides a further incentive to graduates of the MARC Honors Undergraduate Program to obtain research training in the Nation's very best graduate programs.
- o The MARC Faculty Fellowship offers an opportunity for advanced biomedical research training to selected full-time faculty members of minority institutions. This training may lead to a Ph.D. degree or may involve postdoctoral research, and may be pursued at any non-profit, public, or private institution in the United States with suitable facilities. When the training period is over, fellows are expected to return to the sponsoring schools to teach and conduct research.
- o The MARC Visiting Scientist Program provides support for periods of 3 to 12 months to outstanding scientist-teachers who serve as visiting scientists at eligible minority institutions.

The Minority High School Student Research Apprentice Program (MHSSRAP) provides minority high school students with an opportunity for meaningful experience in various aspects of health-related research to stimulate their interest in careers in science. Eligible institutions include over 730 institutions that were awarded either Biomedical Research Support (BRS) or MBRS grants in the last Federal fiscal year. In FY 1990, over 50 percent of the eligible institutions participated in the MHSSRAP program. The National Center for Research Resources plans to increase the number of eligible institutions in the program in FY 1991 in order to accommodate more high school students in the program.

The Minority Institutional Research Training Program supports full-time research training for investigative

careers at minority schools in areas related to cardiovascular, pulmonary, and hematologic diseases. This program is supported by the National Heart, Lung, and Blood Institute.

The goal of the Minority Supplement Program for Research Training Grants, administered by the NIDDK, is to facilitate the recruitment of underrepresented minority graduate students into existing research training grants. The National Institute on Aging and the National Center for Nursing Research have similar programs that support minority postdoctorates and minority graduate students on existing research training grants.

The NIH National Research Service Award (NRSA) Programs train pre- and post-doctoral students in all areas of biomedical research. A special initiative requires that each new or renewal application include a plan to recruit individuals from underrepresented minority groups.

The NIH Visiting Professors Program encourages NIH intramural scientists to visit historically black colleges and universities (HBCUs) for a period from a week to several months to collaborate with HBCU faculty and stimulate their students to seek research careers. This program is supported by the National Institute of Child Health and Human Development.

The Predoctoral Fellowship Awards for Minority Students provides NRSA Individual Fellowship support for minority graduate students from all institutions to pursue careers in biomedical research. Information may be obtained from the National Institute of General Medical Sciences.

The Science Enrichment Program is a six-week residential program for underrepresented minorities and underserved youth that is designed to encourage 10th graders to pursue professional research careers in the fields of science and/or mathematics. This program is administered by the National Cancer Institute.

A Short-term (summer) Training Program supports minority dental students to conduct research in the dental sciences. This program is supported by the National Institute of Dental Research.

The Short-term Training for Minority Students Program supports short-term (i.e., two to three months) research experiences related to cardiovascular, pulmonary, and hematologic diseases. The opportunities are available for minority undergraduate students, minority students in health professional schools, and minority graduate students. This program is offered by the National Heart, Lung, and Blood Institute.

The Summer Research Training Program for Undergraduate Minority Students is a 10-week research experience for undergraduate students who have completed the junior year and who have career goals in the health sciences. The program is supported by the National Institute of Diabetes and Digestive and Kidney Diseases.

Other Fellowship Programs

The NIH Extramural Associates Program sponsors individuals from minority institutions to come to the NIH to learn first-hand about the NIH programs, peer review, and grant administration. Scientist administrators from eligible institutions, including HBCUs, participate in this program. Support is arranged through an Intergovernmental Personnel Act agreement. Since the program's inception in 1978, more than 50 HBCUs have participated in the Extramural Associates Program.

RESEARCH SUPPLEMENTS TO PROMOTE THE RECRUITMENT OF INDIVIDUALS WITH DISABILITIES INTO BIOMEDICAL RESEARCH CAREERS

NIH GUIDE, Volume 21, Number 3, Part I of II, January 24, 1992

P.T. 34, DD; K.W. 0710030, 0720005

National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration

BACKGROUND

A recent report, titled "Changing America: The New Face of Science and Engineering" and issued by the President's Task Force on Women, Minorities, and the Handicapped in Science and Technology, December 1989, has documented a very low participation rate for Americans with disabilities in the science and engineering workforce. To address this problem for the biomedical and behavioral research workforce, the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) and their awarding components have developed an initiative that is designed to extend opportunities to individuals with qualifying disabilities who are capable of entering or resuming research careers. Under this initiative, individuals with disabilities are encouraged to pursue biomedical research careers in areas within the missions of all the awarding components of the NIH and ADAMHA through supplemental awards to certain ongoing research grants. It is hoped that the plan to provide funding at several different stages in a research career will substantially increase the number of individuals with disabilities in biomedical research².

The NIH and ADAMHA hereby notify Principal Investigators holding certain NIH or ADAMHA research grants of the availability of funds for administrative supplements to existing grants for the support and recruitment of scientists and students with disabilities. Supplemental awards are available to support individuals with disabilities from each of the following population groups:

- o High School Students. Supplements under this program are designed to foster an interest in biomedical and behavioral research.
- o Undergraduate Students. This program will support undergraduate students to encourage continuation on to graduate level training in the biomedical and behavioral sciences.
- o Graduate Research Assistants. Graduate students can receive support under this program to develop their research capabilities.
- o Individuals in Postdoctoral Training. This program provides support during postdoctoral training to enable the development of an independent career in biomedical research.
- o Investigators Developing Independent Research Careers. Staff and faculty members with a doctoral degree can receive short- and long-term support for participation in an ongoing research project while further developing their own independent research potential.
- o Established Investigators Who Become Disabled. This program will provide additional support for established NIH and ADAMHA investigators and project leaders on components of program projects and center grants who become disabled. The additional support may be requested for assistants or special equipment that will facilitate a continuing contribution to the NIH research mission. Because this program differs in substantial ways from the other supplemental awards listed here, it is described in a separate below.

GENERAL PROVISIONS

For all of the supplemental programs listed above, the proposed research experience must be an integral part of the approved, ongoing research of the parent grant. Also, with the exception of the supplemental program

¹For the purpose of this announcement, the definition of disabled individuals in the Americans With Disabilities Act will be used. An individual with a disability is one who "has a physical or mental impairment that substantially limits one or more major life activities, a record of such an impairment, or who is regarded as having such an impairment." Qualified individuals with disabilities are those who, with reasonable accommodation for their disability, are capable of entering a research career after appropriate experience and training. A list of disabilities that might confer eligibility for supplemental awards under this program includes, but is not limited to, the following: total deafness in both ears, visual acuity less than 20/200 with corrective lenses, speech impairment, missing extremities, partial paralysis, complete paralysis, convulsive disorders, mental or emotional illness, learning disabilities, kidney dialysis, and severe distortion of limbs and/or spine. In all cases, individuals supported under this supplement program must, with reasonable assistance, be able to contribute to the research supported by the parent grant.

²Application for or acceptable of a research supplement does not alter the requirement that grant recipients must not exclude from participation in any program receiving Federal financial assistance an otherwise qualified, disabled individual solely by reason of the disability. In addition, grant recipients must make reasonable accommodation to the known physical or mental limitations of an otherwise qualified disabled individual unless the recipient can demonstrate that the accommodation would impose an undue hardship on the operation of the recipient's program.

for Established Investigators Who Become Disabled, which is described in a separate section, individuals with disabilities must be given the opportunity to interact with individuals on the parent grant, to contribute intellectually to the research, and to enhance his/her research skills and knowledge regarding the particular area of biomedical science. Furthermore, the Principal Investigator must demonstrate a willingness and understanding that the purpose of the award is to enhance the research capability of the student or faculty member with a disability, and that the research experience is intended to provide opportunities for individuals with disabilities to develop into independent, competitive research investigators. All awards made under these programs will be consistent with the goals of strengthening the existing research program and the overall programmatic balance and priorities of the funding component at the NIH and ADAMHA. Awards will be made according to the policies and provisions stated in this announcement.

Applicants are encouraged to contact the NIH and ADAMHA institute staff identified in the INQUIRIES section below prior to submission in order to obtain specific information about application characteristics and requirements. It is also recognized that individual circumstances vary and, for unusual situations, NIH and ADAMHA program administrators should be consulted for a determination of eligibility.

REASONABLE ACCOMMODATIONS

As a part of these awards, funds may be requested to make changes or adjustments in the research setting that will make it possible for an otherwise qualified employee with disabilities to perform the essential functions associated with his/her role on the project. The accommodations requested under this program must be DIRECTLY related to the performance of the proposed role on the research project and must be appropriate to the disabilities of the individual. Some types of accommodations that might be provided under these awards include: specialized equipment, assistive devices, and personnel such as readers, interpreters, or assistants. In all cases, the total funds for accommodations requested from the supplement must be reasonable in relationship to the direct costs of the parent grant and the nature of the supplemental award.

ELIGIBILITY

Research Grants Eligible for Supplemental Awards: Any Principal Investigator at a domestic institution holding an active Research Centers in Minority Institutions Award (G12), Research Project (R01), Cooperative Clinical Research (R10), Research Demonstration and Dissemination Projects (R18), U.S. - Japan Cooperative Medical Science Program (R22), Resource-Related Research Projects (R24), Outstanding Investigator Grants (R35), Method to Extend Research in Time (MERIT) (R37), Research Program Projects (P01), Exploratory Grants (P20), Center Core Grants (P30), Animal (Mammalian and Non-mammalian) Model, and Animal and Biological Materials Resource Grants (P40), Biotechnology Resource Grant Program (P41), Specialized Center (P50), Comprehensive Center (P60), Cooperative Agreement (U01), or Cooperative Clinical Research (U10) is eligible to submit a request for an administrative supplement to the awarding component of the parent grant. Principal Investigators holding an active First Independent Research Support and Transition (FIRST) Award (R29) also may apply for a supplement under this program, but only when the candidate with disabilities is a high school student, an undergraduate student, or a graduate student. Supplements for individuals with disabilities on R29 awards may provide support above the dollar limits on these awards.

In all cases, the parent grant must have support remaining for a reasonable period at the time of a supplemental award. Principal Investigators are encouraged to submit an application no later than three months before the anniversary date of the last two years remaining on the parent grant.

Usually, each parent grant may have only one supplement for a person with disabilities. Appointment of more than one individual to a single grant under these supplement programs will be considered depending on the nature of the parent grant, the circumstances of the request, and the program balance of the awarding component. Supplemental awards under these programs do not preclude a separate supplement to support an underrepresented minority (See NIH Guide for Grants and Contracts, Vol. 2, No. 3, Part 1 of 2, January 24, 1992).

Candidates Eligible for Support by a Supplemental Award: The purpose of the request will be to support a high school student, an undergraduate student, a graduate research assistant, an individual in postdoctoral training, or a staff or faculty member with disabilities to participate in ongoing research projects. Awards will be limited to citizens, non-citizen nationals of the United States, and individuals who have been lawfully admitted for permanent residence (i.e., in possession of an Alien Registration Receipt Card) at the time of application. Other specific eligibility requirements relative to each type of award are set forth in the individual program descriptions below.

Individuals with disabilities may receive support under these programs on only one grant at any time, but may be supported by more than one grant during the development of their research careers. Support under the supplement programs is not transferable to another individual.

The research supplement programs for individuals with disabilities have been designed to attract disabled individuals into research careers and are not intended to provide an alternative means of supporting disabled individuals who are already supported by research grants or other Public Health Service (PHS) mechanisms. If the Principal Investigator wishes to transfer an individual with disabilities to supplemental support from an existing PHS supported position, the reason for the transfer must be clearly documented. Individuals may not be transferred to supplemental support simply to increase the availability of funds on the parent grant for other uses such as for supplies and travel. Disabled graduate students or disabled individuals in postdoctoral training who are supported by a National Research Service Award (NRSA) research training grant may not be transferred to supplemental support prior to the completion of their appointed period of training.

APPLICATION PROCEDURES

A request for a supplement may be submitted at any time. IN MAKING REQUESTS, THE GRANTEE INSTITUTION, ON BEHALF OF THE PRINCIPAL INVESTIGATOR OF THE PARENT GRANT AND IN COOPERATION WITH THE INDIVIDUAL WITH DISABILITIES, MUST SUBMIT THE REQUEST FOR SUPPLEMENTAL FUNDS DIRECTLY TO THE AWARDING COMPONENT THAT SUPPORTS THE PARENT GRANT. The request is not to be submitted to the NIH Division of Research Grants. Principal Investigators are encouraged to obtain the exact address for submission from the NIH and ADAMHA program administrator on the parent grant.

The request for a supplemental award must include the following:

1. A completed face page (with appropriate signatures) from Grant Application Form PHS 398. Include the title and grant number of the parent grant in Item 1 and indicate which type of supplement is being requested in Item 2.
2. A brief three to four page description, prepared by the Principal Investigator of the parent grant, that includes:
 - o A summary or abstract of the funded grant or project.
 - o A description of the research experience proposed for the disabled individual.
 - o How the research experience will expand and foster the training or independent research capabilities of the candidate.
 - o How the research experience will relate to the specific research goals and objectives of the parent grant.
3. A statement from the candidate with disabilities outlining his/her research objectives and career goals.
4. The social security number and biographical sketch of the candidate that includes evidence of scientific achievement or interest.
5. A statement from the institution that establishes the eligibility of the individual with disabilities for support under this program. This must include information certifying the individual's citizenship, the nature of the disability, any occupational limitations associated with the disability, and the types of accommodations that will permit the individual to undertake the proposed research experience. Also, the institution must indicate its contribution to aid accommodation of the candidate to the research environment.
6. A proposed budget entered on budget pages from Grant Application Form PHS 398, including the proposed salary and percent effort (where appropriate) for the research experience in the first and future years. All special accommodations requested must be detailed and justified in the budget section. If the initial budget period requested is less than 12 months, the budget should be prorated accordingly.
7. Documentation, if applicable, that the proposed research experience was approved by the Institutional Animal Care and Use Committee (IACUC) or human subjects Institutional Review Board (IRB) of the grantee institution.
8. A copy of an official transcript if the candidate is a student.
9. If the individual with disabilities is a student at another institution, the application also must include an appropriately signed letter from a responsible official at the institution of matriculation indicating that participation at the stated level of effort is approved and will not detract from or interfere with his/her course of studies.
10. If any of the research is to be conducted at a site other than the grantee institution, an appropriately signed letter from the institution where the research is to be conducted must be submitted.

The request must be signed by the individual with disabilities, the Principal Investigator, and the appropriate institutional business official.

REVIEW CRITERIA

The staff of the particular awarding component will review requests for supplements using the following general criteria:

- o The qualifications of the individual with disabilities including career goals, prior research training, relevant experience, and the potential for a research career after appropriate experience and training.
- o The plan for the proposed research experience in the supplemental request and its relationship to the parent grant.
- o The appropriateness of the proposed accommodations for the candidate and his/her role on the research project. The appropriateness of the costs of the proposed accommodations to be paid from the supplement relative to the cost of the parent project and the nature of the requested supplemental award. Evidence that the proposed accommodations, including those provided by the grantee institution, will be sufficient to enable the candidate to adapt to the research environment.

- o Evidence from the Principal Investigator that the experience will enhance the research potential, knowledge, and/or skills of the candidate.
- o Evidence from the Principal Investigator that the activities of the individual with disabilities will be an integral part of the project.
- o Evidence of educational achievement and interest in science if the candidate is a student.

Additional criteria related to the specific programs may also apply and are described below.

FUNDING

The decision to fund a supplement will take six to eight weeks from the time the completed application is received. Applicants for summer-only research appointments must submit early enough to ensure that funding and accommodations are in place by the time the summer experience is scheduled to begin. In most cases, during the first budget period, funds will be provided as an administrative supplement to the parent grant. In subsequent years, continued funding for the supplement is contingent on funding of the parent grant and cannot extend beyond the current competitive segment of the parent grant.

The continuation of support for the individual with disabilities in the remaining years of the competitive segment of the grant will depend upon a satisfactory review by the awarding component of progress on both the parent grant and the supplemental project, the research proposed for the next budget period, and the appropriateness of the proposed budget to the proposed effort.

In non-competing applications, the progress report for the supplement for the individual with disabilities must be clearly delineated from the progress report for the parent grant. The progress report in both non-competing and competing applications must include information about the research activities supported by the supplement even if support for future years is not requested. In future competing applications, funds for continuation of the supplement must be requested in the parent grant application and may NOT be requested as a research supplement.

At the time of each appointment or reappointment in a new budget period, the individual supported by a supplement for individuals with disabilities must complete a Statement of Appointment Form (Form PHS 2271, revision 9/91).

DESCRIPTION OF THE INDIVIDUAL RESEARCH SUPPLEMENT PROGRAMS

1. High School Students

The purpose of this program is to provide disabled high school students, who have demonstrated an interest and an aptitude for scientific pursuits, with a meaningful experience in various aspects of health-related research to stimulate interest in a career in science.

ELIGIBILITY

Any qualified high school student with disabilities who is enrolled in good standing at a local high school and is interested in biomedical or behavioral research is encouraged to participate in this program.

PROVISIONS

A high school student can receive up to \$2,000 for supplies and salary during a summer experience. A part-time experience during the regular school year would be reimbursed at the same rate. Funds over and above this \$2,000 limit may be requested to permit accommodation to the research environment. This may include research equipment if it is directly related to both the project AND to accommodating the disabilities of the student. In all cases, equipment may only be purchased with prior approval of the NIH or ADAMHA awarding component.

Students are expected to devote sufficient effort to the research project and related activities during the period of support to gain insight into the process of scientific discovery. Support may be for a minimum of three months during any one year which may include a mixture of full-time summer experience and part-time experience during the school year. Principal Investigators are encouraged to seek high school students who will devote at least two years to this program (i.e., equivalent to two three-month, full-time, periods). Exceptions to the latter will be considered, depending on the circumstances of the applicant, the parent grant, and the specific request.

See the GENERAL PROVISIONS section (above) for information about application procedures, review criteria, and funding.

2. Undergraduate Students

DESCRIPTION

This supplemental program provides an opportunity for any qualified undergraduate student with disabilities, who is interested in biomedical or behavioral research, to participate in a research project at a research institution during the summer months or during the school year. This experience will be separate and apart from any requirement of the regular academic program.

The success of this program is dependent on the ability of the Principal Investigator to identify appropriate students. A number of procedures may be used to match investigators to appropriate college students: (1) the Principal Investigator may identify a student and initiate the request for the supplement; (2) the institution may make the pairing of the student with the Principal Investigator; (3) the student may contact a grantee institution or an investigator and request a research experience.

ELIGIBILITY

The student may be affiliated with either the applicant institution or any other academic institution. Any qualified undergraduate student with disabilities who is interested in biomedical or behavioral research is encouraged to participate in this program.

PROVISIONS

This supplement is not to exceed \$6.00 per hour for salary plus \$125 per month for supplies and travel. Funds over and above this limit may be requested to permit accommodation to the research environment. This may include research equipment, but only if it is directly related to both the project AND to accommodating the disabilities of the student. In all cases, equipment may only be purchased with prior approval of the NIH or ADAMHA awarding component.

Students are expected to devote an equivalent of at least three months full-time effort to the research project and related activities in any one year, and in most cases the period of support for any individual should last at least two years. Exceptions to the latter will be considered, depending on the circumstances of the applicant, the parent grant, and the specific request.

See the GENERAL PROVISIONS section (above) for information about application procedures, review criteria, and funding.

3. Graduate Research Assistants

DESCRIPTION

The objective of this program is to offer additional encouragement to graduate students with disabilities who have the potential to become researchers in biomedical or behavioral sciences and give them an opportunity to develop their research capability further.

ELIGIBILITY

Any graduate student with disabilities who is enrolled in a masters or a doctoral degree program in biomedical or behavioral sciences is eligible for consideration.

PROVISIONS

The NIH and ADAMHA will provide salary support in addition to other necessary expenses, such as supplies and travel, to enable the individual to participate as a graduate research assistant in funded research projects. The requested salary must be in accordance with the salary structure of the grantee institution and consistent with the level of effort. Funds may also be requested to permit accommodation to the research environment. This may include research equipment, but only if it is directly related to both the project AND to accommodating the disabilities of the student. In all cases, equipment may only be purchased with prior approval of the NIH or ADAMHA awarding component.

See the GENERAL PROVISIONS section (above) for information about application procedures, review criteria, and funding.

4. Individuals in Postdoctoral Training

DESCRIPTION

These supplements provide support to individuals with disabilities in the postdoctoral phase of training to participate in ongoing research projects that will assist in the development of a career in biomedical or behavioral research.

ELIGIBILITY

The individual in postdoctoral training may be affiliated with either the applicant institution or any other institution. Only under extraordinary circumstances, that must be well justified in the application, would it be acceptable for the candidate to continue working with his/her former predoctoral mentor.

PROVISIONS

Support will be provided for a salary in addition to other necessary expenses, such as supplies and travel, to enable the individual to participate as a postdoctoral research assistant in funded research projects. The requested salary must be in accordance with the salary structure of the grantee institution and consistent with the level of effort. Funds may also be requested to permit accommodation to the research environment. This may include research equipment, but only if it is directly related to both the project AND to accommodating the disabilities of the individual. In all cases, equipment may only be purchased with prior approval of the NIH

or ADAMHA awarding component.

See the GENERAL PROVISIONS section (above) for information about application procedures, review criteria, and funding.

5. Investigators Developing Independent Research Careers

DESCRIPTION

These supplements provide either short- or long-term research support for staff or faculty members with disabilities to enhance their research skills leading to an independent research career.

Short-term Investigator Research Supplement. This supplement provides short-term support for staff or faculty members to conduct full-time research for three to five months each year, during the summer or another portion of the academic year, over a maximum period of four years.

Long-term Investigator Research Supplement. This supplement provides long-term research support for staff or faculty members to conduct research in the biomedical or behavioral sciences. Support is provided for up to four years at a minimum of 30 percent effort during each 12-month period.

ELIGIBILITY

The investigator with disabilities may be affiliated with either the applicant institution or any other institution. The investigator must have a doctoral degree, be beyond the level of a research trainee, be a member of the staff or faculty, and have at least one year of postdoctoral experience. The investigator may have received prior research or research training support from the NIH or ADAMHA or support under the Minority Biomedical Research Support (MBRS), Minority Access to Research Careers (MARC), small grants, or Academic Research Enhancement Awards (AREA) programs. But, an individual who has received independent research support as a Principal Investigator on an individual research grant (e.g., R01, R29) or as a project leader on a program project or center grant (e.g., P01, P50), or as a Principal Investigator on an individual research career award (e.g., K02, K04, K08) is not eligible for support under this program. See the special exception to this restriction for currently funded, established investigators who become disabled (see section 6).

PROVISIONS

The faculty or staff supplemental award is for a maximum of \$50,000 in direct costs per year. A maximum of \$40,000 may be requested for salary and fringe benefits. Funds up to \$10,000 may also be requested for research supplies and travel. Funds over and above this \$50,000 limit may be requested to permit accommodation to the research environment. This may include research equipment, but only if it is directly related to both the project AND to accommodating the disabilities of the investigator. In all cases, equipment may only be purchased with prior approval of the NIH or ADAMHA awarding component. The maximum period of support for any investigator is four years.

The amount of salary requested must be consistent with the policies of the parent grantee institution (and, if applicable, the disabled investigator's employing institution) and must be related to the percent effort of the investigator.

See the GENERAL PROVISIONS section (above) for application procedures, review criteria, and funding.

6. Supplements for Established Investigators who Become Disabled

DESCRIPTION

Established investigators on NIH or ADAMHA research, program project, or center grants, who become disabled during the current project period, may request special accommodations to permit completion of the currently funded research project.

ELIGIBILITY

Any currently funded Principal Investigator or Co-Investigator or other senior staff (hereinafter referred to as Established Investigator) on an NIH or ADAMHA research project grant, program project grant, or center grant may request support for special equipment, an assistant, or other modifications to facilitate accommodation to a disabling injury or illness that has occurred during the current project period.

PROVISIONS

Support will be limited to items that will permit the investigator to complete the remaining years of a currently funded research project. This might include: salary support for an individual who can assist the Established Investigator in meeting the goals of the research project, specialized equipment, such as computers, or modifications of the working environment. In all cases, the requested support must be consistent with the type of disability and the nature of the approved research. The total amount of support requested under this supplement must be reasonable in relationship to the direct costs of the parent award and the Established Investigator's role and effort on the project. In future competing applications, funds for continuation of the accommodations provided under this supplement must be requested in the parent grant application and may NOT be requested as a research supplement.

APPLICATION PROCEDURES

A request for a supplement may be submitted at any time. In making requests, the grantee institution, on behalf of the Established Investigator, must submit the request for supplemental funds directly to the awarding component that supports the parent grant. The request must include the following:

- o A completed face page from Grant Application Form PHS 398 with the title and grant number of the parent grant and a statement that specifies which type of supplement is being requested.
- o A statement by the Established Investigator describing the nature of the disability and the attendant limitations on his/her capacity to complete the goals established for the current project period.
- o A statement from the institution certifying the disability and describing the types of accommodations requested and their relationship to the research project and the disabilities of the Established Investigator.
- o A proposed budget entered on budget pages from Grant Application Form PHS 398. The budget must reflect all special accommodations to support the adaptation of the Established Investigator to the research environment.

The request must be signed by the Principal Investigator, the Established Investigator with disabilities (if other than the Principal Investigator), and the appropriate institutional business official.

REVIEW CRITERIA

The staff of the particular awarding component will review requests for supplements using the following criteria:

- o The appropriateness of the proposed accommodations for the Established Investigator regarding his/her role on the research project and the nature of the disability.
- o The appropriateness of the cost of the proposed accommodations to be paid from the supplement in relationship to the total direct cost of the parent project.

FUNDING

See the section on funding in the GENERAL PROVISIONS section, above.

INQUIRIES

Principal Investigators interested in participating in any of these supplemental programs are encouraged to contact NIH or ADAMHA staff administering the parent grant. For general information about the Supplements for Individuals with Disabilities, contact the following staff person in the appropriate awarding component:

NATIONAL INSTITUTES OF HEALTH

National Institute on Aging
Deputy Associate Director
Office of Extramural Affairs
Building 31, Room 5C02
Bethesda, MD 20892
Telephone: (301) 496-9322

National Institute of Allergy and Infectious Diseases
Assistant Director, Division of Extramural Activities
Westwood Building, Room 7A03
Bethesda, MD 20892
Telephone: (301) 496-5030

National Institute of Arthritis and Musculoskeletal and Skin Diseases
Director, Extramural Programs
Westwood Building, Room 705
Bethesda, MD 20892
Telephone: (301) 402-0159

National Institute of Child Health and Human Development
Special Assistant to the Deputy Director
Building 31, Room 2A03
Bethesda, MD 20892
Telephone: (301) 496-0104

National Institute on Deafness and Other Communication Disorders
Director, Division of Extramural Activities
6120 Executive Blvd., EPS-400B
Rockville, MD 20892
Telephone: (301) 496-8693

National Institute of Dental Research
Director, Extramural Program
Westwood Building, Room 503
Bethesda, MD 20892
Telephone: (301) 496-7723

National Institute of Diabetes and Digestive and Kidney Diseases
Assistant Director for Grants and Contracts
Division of Extramural Activities
Westwood Building, Room 657
Bethesda, MD 20892
Telephone: (301) 496-7793

National Institute of Environmental Health Sciences
Director, Division of Extramural Research and Training
Building 3, Room 301A
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-7723

National Institute of General Medical Sciences

For general information contact:

Assistant Director
Referral and Liaison, NIGMS, NIH
Westwood Building, Room 925
Bethesda, MD 20892
Telephone: (301) 402-0593

For information on procedures for initiating an application for a supplement, contact the program administrator of the parent grant, or:

Deputy Associate Director
Office of Program Activities, NIGMS, NIH
Westwood Building, Room 938
Bethesda, MD 20892
Telephone: (301) 496-7063

National Institute of Neurological Disorders and Stroke
Deputy Director, Division of Extramural Activities
Federal Building, Room 1016
Bethesda, MD 20892
Telephone: (301) 496-4188

National Cancer Institute
Director, Division of Extramural Activities
Building 31, Room 10A03
Bethesda, MD 20892
Telephone: (301) 496-5147

National Eye Institute
Research Training and Resources Officer
Building 31, Room 6A48
Bethesda, MD 20892
Telephone: (301) 496-5983

National Heart, Lung, and Blood Institute
Director, Division of Extramural Affairs
Westwood Building, Room 7A17B
Bethesda, MD 20892
Telephone: (301) 496-7416

National Center for Nursing Research
Director, Extramural Programs
Building 31, Room 5B03
Bethesda, MD 20892
Telephone: (301) 496-0523

National Library of Medicine
Acting Associate Director, Division of Extramural Programs
Building 38A, 5N505
Bethesda, MD 20892
Telephone: (301) 496-4621

National Center for Research Resources
Deputy Director for Extramural Research Resources
Building 12A, Room 4011
Bethesda, MD 20892
Telephone: (301) 496-6023



3 1496 00483 1593

National Center for Human Genome Research
Chief Research Grants Branch
Building 38A, Room 612
Bethesda, MD 20892
Telephone: (301) 496-7531

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute on Alcohol Abuse and Alcoholism
Associate Director, Division of Basic Research
Parklawn Building, 16C-06
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-2530

National Institute on Drug Abuse
Public Health Analyst, Science Policy and Analysis Branch
Office of Science Policy
Parklawn Building, 10A-54
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-6071

National Institute of Mental Health
Associate Director, Research Training and Research Resources
Division of Clinical Research
Parklawn Building, 10-95
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-3264

National Institute of Mental Health
Associate Director, Research Training and Research Development
Division of Basic Brain and Behavioral Sciences
Parklawn Building, 11-95
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4347

National Institute of Mental Health
Associate Director, Research Training
Division of Applied and Services Research
Parklawn Building, 18C-26
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-3685

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21, No. 3, Part II of II
January 24, 1992

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NOTICES OF AVAILABILITY (RFPs AND RFAs)

EVALUATION OF THE TOXIC AND CARCINOGENIC POTENTIAL OF ISOPRENE, INDIUM PHOSPHIDE, AND GALLIUM ARSENIDE WHEN INHALED IN FISCHER 344/N RATS AND B6C3F1 MICE

NIH GUIDE, Volume 21, Number 3, Part II of II, January 24, 1992

RFP AVAILABLE: NIH-ES-92-17

P.T. 34; K.W. 1007009, 0715035

National Institute of Environmental Health Sciences

The purpose of this contract is to evaluate the toxic and carcinogenic potential of isoprene, gallium arsenide, and indium phosphide when inhaled in Fischer 344/N rats and B6C3F1 mice. The base contract award will include work activities associated with bulk chemistry, generation and monitoring developmental work, and health and safety concerns. The Government may, pending the availability of funds, exercise options for: an inhalation study of glutaraldehyde, a 104-week chronic study of glutaraldehyde, a 104-week chronic study of isoprene; a 104-week chronic study of gallium arsenide; a 13-week study of indium phosphide, and a 104-week chronic study of indium phosphide. These studies shall be conducted in accordance with the Food and Drug Administration (FDA) Good Laboratory Practice Regulations as specified in Part 58 "Good Laboratory Practices for Nonclinical Laboratory Studies" (Federal Register, Friday, December 22, 1978, Part II and any later interpretations published by the FDA).

Award of one cost-reimbursement, completion-type contract with an estimated period of performance for the base contract of approximately one year on an open competition basis is contemplated as a result of this solicitation. Exercise of all options under this solicitation may result in a multi-year cost-reimbursement type contract with a total term of four years nine months that would be incrementally funded. All responsible sources may submit a proposal that will be considered by the Agency. Expected release date of the RFP is January 27, 1992, with proposals due March 12, 1992.

Requests should reference RFP NIH-ES-92-17 and be sent to:

Contracts and Procurement Management Branch, OM
National Institute of Environmental Health Sciences
ATTN: Marilyn B. Whaley, Contract Specialist
79 T.W. Alexander Drive, 4401 Building
P.O. Box 12874
Research Triangle Park, NC 27709
Telephone: (919) 541-5770

EVALUATION OF THE TOXIC AND CARCINOGENIC POTENTIAL OF SODIUM FLUORIDE AND METHYLEUGENOL ADMINISTERED ORALLY IN LABORATORY ANIMALS

NIH GUIDE, Volume 21, Number 3, Part II of II, January 24, 1992

RFP AVAILABLE: NIH-ES-92-18

P.T. 34; K.W. 1007009, 0715035, 0740021

National Institute of Environmental Health Sciences

The purpose of this contract is to evaluate the toxic and carcinogenic potential of sodium fluoride and methyleugenol administered orally in laboratory animals. The base contract award will include work activities associated with bulk chemistry, dose formulation and dose analysis developmental work, and health and safety concerns. The Government may, pending the availability of funds, exercise options for: a study of anthraquinone, a 13-week study of anthraquinone, a 104-week chronic study of anthraquinone, a 104-week chronic study of sodium fluoride, and a 104-week chronic study of methyleugenol. Laboratory animals, that will be used in these studies are Fischer 344/N rats and B6C3F1 mice. These studies shall be conducted in accordance with the Food and Drug Administration (FDA) Good Laboratory Practice Regulations as specified in Part 58 "Good Laboratory Practices for Nonclinical Laboratory Studies" (Federal Register, Friday, December 22, 1978, Part II and any later interpretations published by the FDA).

Award of one cost-reimbursement, completion type contract with an estimated period of performance for the base contract of approximately ten months on an open competition basis is contemplated as a result of this solicitation. Exercise of all options under this solicitation may result in a multi-year cost-reimbursement type contract with a total term of five years ten months that would be incrementally funded. All responsible sources may submit a proposal that will be considered by the Agency. Expected release date of the RFP is January 27, 1992, with proposals due March 12, 1992.

Requests should reference RFP NIH-ES-92-18 and should be forwarded to:

Contracts and Procurement Management Branch, OM
National Institute of Environmental Health Sciences
ATTN: Marilyn B. Whaley, Contract Specialist
79 T.W. Alexander Drive, 4401 Building
P.O. Box 12874
Research Triangle Park, NC 27709
Telephone: (919) 541-5770

EVALUATION OF THE TOXIC AND CARCINOGENIC POTENTIAL OF SODIUM NITRITE AND O-NITROTOLUENE ADMINISTERED ORALLY IN LABORATORY ANIMALS

NIH GUIDE, Volume 21, Number 3, Part II of II, January 24, 1992

RFP AVAILABLE: NIH-ES-92-19

P.T. 34; K.W. 1007009, 0715035, 0740021

National Institute of Environmental Health Sciences

The purpose of this contract is to evaluate the toxic and carcinogenic potential of sodium nitrite and o-nitrotoluene administered orally in laboratory animals. The base contract award will include work activities associated with bulk chemistry, dose formulation and dose analysis developmental work, and health and safety concerns. The Government may, pending the availability of funds, exercise options for: a study of Cinnamaldehyde; a 13-week study of cinnamaldehyde, a 104-week chronic study of cinnamaldehyde, a 104-week chronic study of sodium nitrite, and a 104-week chronic study of o-nitrotoluene. Laboratory animals, that will be used in these studies, are Fischer 344/N rats and B6C3F1 mice. These studies shall be conducted in accordance with the Food and Drug Administration (FDA) Good Laboratory Practice Regulations as specified in Part 58 "Good Laboratory Practices for Nonclinical Laboratory Studies" (Federal Register, Friday, December 22, 1978, Part II and any later interpretations published by the FDA).

Award of one cost-reimbursement, completion-type contract with an estimated period of performance for the base contract of approximately ten months on an open-competition basis is contemplated as a result of this solicitation. Exercise of all options under this solicitation may result in a multi-year, cost-reimbursement type contract with a total term of five years six months that would be incrementally funded. All responsible sources may submit a proposal that will be considered by the Agency. Expected release date of the RFP is January 27, 1992, with proposals due March 12, 1992.

Requests should reference RFP NIH-ES-92-19 and be forwarded to:

Contracts and Procurement Management Branch, OM
National Institute of Environmental Health Sciences
ATTN: Marilyn B. Whaley, Contract Specialist
79 T.W. Alexander Drive, 4401 Building, P.O. Box 12874
Research Triangle Park, NC 27709
Telephone: (919) 541-5770

EVALUATION OF THE TOXIC AND CARCINOGENIC POTENTIAL OF CITRAL ADMINISTERED ORALLY IN LABORATORY ANIMALS

NIH GUIDE, Volume 21, Number 3, Part II of II, January 24, 1992

RFP AVAILABLE: NIH-ES-92-20

P.T. 34; K.W. 1007009, 0715035, 0740021

National Institute of Environmental Health Sciences

The purpose of this contract is to evaluate the toxic and carcinogenic potential of citral administered orally in laboratory animals. The base contract award will include work activities associated with bulk chemistry, dose formulation and dose analysis developmental work, and health and safety concerns. The Government may, pending the availability of funds, exercise options for: a study of 1,4-butanediol, a 13-week study of 1,4-butanediol, a 104-week chronic study of 1,4-butanediol, a 13-week study of citral, and, a 104-week chronic study of citral. Laboratory animals, that will be used in these studies are Fischer 344/N rats and B6C3F1 mice. These studies shall be conducted in accordance with the Food and Drug Administration (FDA) Good Laboratory Practice Regulations as specified in Part 58 "Good Laboratory Practices for Nonclinical Laboratory Studies" (Federal Register, Friday, December 22, 1978, Part II and any later interpretations published by the FDA).

Award of one cost-reimbursement, completion-type contract with an estimated period of performance for the base contract of approximately four months as a set-aside for a small business concern is contemplated as a result of this solicitation. Exercise of all options under this solicitation could result in a multi-year, cost-reimbursement type contract with a total term of five years six months that would be incrementally funded. All responsible sources may submit a proposal that will be considered by the Agency. Expected release date of the RFP is January 27, 1992 with proposals due March 12, 1992.

Requests should reference RFP NIH-ES-92-20 and be forwarded to:

Contracts and Procurement Management Branch, OM
National Institute of Environmental Health Sciences
ATTN: Marilyn B. Whaley, Contract Specialist
79 T.W. Alexander Drive, 4401 Building
P.O. Box 12874
Research Triangle Park, NC 27709
Telephone: (919) 541-5770

EXPLORATORY CENTERS FOR BIOBEHAVIORAL SYMPTOM MANAGEMENT

NIH GUIDE, Volume 21, Number 3, Part II of II, January 24, 1992

RFA AVAILABLE: NR-92-02

P.T. 04; K.W. 0715020, 0785130, 0404000, 0785035, 0710030

National Center for Nursing Research

Letter of Intent Receipt Date: March 31, 1992
Application Receipt Date: May 7, 1992

PURPOSE

The National Center for Nursing Research (NCNR) announces the availability of a Request for Applications (RFA) for exploratory centers (P20) for the development of innovative clinical assessment and management strategies for symptoms commonly experienced by acutely or chronically ill patients. These clinical assessment and management strategies must address the biological and behavioral interface of the selected symptom(s). The center must have an interdisciplinary approach with a focus on clinical research, basic research, or a combination.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Exploratory Centers for Biobehavioral Symptom Management, is related to the priority areas of cancer, heart disease, and stroke, and diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted from domestic, for-profit and non-profit, public and private universities, colleges, hospitals, or medical centers. Applications from foreign institutions are ineligible for the center program mechanism. Although there are no requirements for the presence of funded research grants, pilot studies that are based on prior studies and an evolving program of research will be more competitive. Those applicant institutions with ongoing funded research projects, such as R01s, must explain the appropriateness of the exploratory center mechanism for their institution and how science will be advanced for the symptom(s) selected. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The support mechanism for this RFA is the exploratory center grant (P20). The exploratory center grant must consist of (1) an administrative and planning core providing administrative, coordinating, planning, logistical, and/or methodological (e.g., research design, data analysis) support and (2) feasibility/pilot studies. The initial award period is for three years, and the award may not be renewed.

Applicants for exploratory center grants may request up to three years of support at a maximum of \$125,000 total costs per year.

The majority of the funds under this RFA will be devoted to small-scale studies. The Administrative and Planning Core may not exceed 20 percent of the direct costs. The anticipated award date for the grants is September 30, 1992.

FUNDS AVAILABLE

Approximately \$300,000 for the first year will be committed to fund applications submitted in response to this RFA. It is anticipated that a minimum of two applications will be funded. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCNR, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

This initiative directly builds on the ongoing work of a panel of scientific experts on symptom management convened as part of the development of the National Nursing Research Agenda. There has been a great deal of

interest in the assessment and management of symptoms experienced by patients both in clinical settings and in home settings.

The goal of this RFA is to stimulate the development of innovative clinical assessment and management strategies for acutely and chronically ill patients in order to more effectively handle the more commonly experienced symptoms. These innovative clinical assessment and management strategies may focus on the prevention of the symptom(s), the amelioration of the symptom(s), or the attenuation of the symptom(s) and continuing occurrence if total alleviation is not possible. These innovative clinical assessment and management strategies must address the biological and behavioral interface of the symptom(s) being considered. Specific behavioral and/or psychosocial strategies need to be matched with specific state-of-the-art biological, chemical, and immunological measurements and techniques to provide a comprehensive picture of the symptom(s) being explored. For example, depression and fatigue are two biological and psychological stress responses during recovery of a myocardial infarction. Immunological, chemical, and biological indices of recovery might include hematological parameters, lymphocytic levels, and electrocardiographic readings. Understanding the biological basis of the symptom(s) manifested by acutely and chronically ill patients will increase the scientific knowledge base for these symptoms and promote the development of behavioral strategies that could be generalized across a variety of patient populations in the future.

The theoretical basis for the planned feasibility/pilot studies must be clearly explicated for the behavioral, psychosocial, and physiological strategies described in the exploratory center grant application. The symptom(s) for exploration is to be selected by the applicants and may include, but is not limited to, the high priority symptoms of pain, fatigue, dyspnea, nausea, vomiting, cognitive impairment, altered sleep or rest patterns, and depression or anxiety secondary to a physical illness. However, symptoms specific to psychiatric disorders are included in the scope of this RFA. One or more symptoms may be selected by each applicants depending on the scientific expertise available at the applicant institution or clinical setting and the theoretical basis chosen to explicate the research. An interdisciplinary approach must be utilized. Although feasibility/pilot studies addressing only pharmacological interventions are not acceptable, the inclusion of pharmacological strategies in combination with nonpharmacologic strategies is appropriate for a multimodal management approach.

Selected symptoms are highlighted in the full RFA to reflect the critical need to develop innovative clinical assessment and management of symptoms commonly experienced by acutely and chronically ill patients. Although specific research needs are identified, they are provided only to stimulate creative research ideas and not to be considered as all inclusive or limiting in scope. The three symptoms selected were ones considered by the expert panel on symptom management, but no specific symptom (or its underlying disease or life event) will be given preferential treatment during the review and funding processes. The scientific merit of the entire exploratory grant application is the crucial element to be considered in the review and funding processes.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit by March 31, 1992, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which an application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It helps NCNR staff estimate the potential review workload and avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Ethel Jackson, D.D.S.
Chief and Scientific Review Administrator
National Center for Nursing Research
Building 31, Room 5B19
9000 Rockville Pike
Bethesda, MD 20892

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 10/88) must be used in applying for these grants. These forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892 (telephone 301-496-7441). Special application instructions apply to the exploratory centers program RFA; and are included in the RFA.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete

applications will be returned to the applicant without further consideration. Those applications that are complete and responsive will be evaluated in accordance with the criteria stated in the RFA for scientific/technical merit by an appropriate peer review group convened by the NCNR. Applications may be subjected to triage by a peer review group to determine competitiveness relative to the other applications received in response to this RFA. The review criteria for triage are identified in the RFA. The NIH will withdraw from further competition those applications judged by triage to be noncompetitive for award and notify the applicant and institutional official. Those applications judged to be competitive will undergo further scientific merit review. The second level of review will be provided by the National Advisory Council for Nursing Research.

AWARD CRITERIA

Applications selected for funding will be from schools of nursing, departments of nursing, or other programs that have appropriately prepared individuals for research. In order to expand the number of researchers conducting research and additional nursing research programs, institutions whose schools of nursing or departmental components have been selected for funding under previous NCNR Centers program RFAs (P50, P20) will not be selected for funding under this RFA.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Laura A. James, Ph.D., R.N.
Nurse Scientist Administrator
Acute and Chronic Illness Branch
National Center for Nursing Research
Building 31, Room 5B03
Bethesda, MD 20892
Telephone: (301) 496-0523

Direct inquiries regarding fiscal matters to:

Sally Nichols
Grants Management Officer
National Center for Nursing Research
Building 31, Room 5B06
Bethesda, MD 20892
Telephone: (301) 496-0237

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.336, Nursing Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review, April 6, 1988.

IMPLEMENTATION GRANTS FOR GENE THERAPY PROGRAMS IN CANCER TREATMENT

NIH GUIDE, Volume 21, Number 3, Part II of II, January 24, 1992

RFA AVAILABLE: CA-92-13

P.T. 34; K.W. 0715035, 0745032, 0755015, 0710030

National Cancer Institute

Letter of Intent Receipt Date: April 3, 1992
Application Receipt Date: May 15, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE COMPLETE RFA FROM THE CONTACT NAMED IN INQUIRIES.

PURPOSE

The Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI) invites program project grant applications (P01) from interested investigators to establish interactive Gene Therapy Programs (GTPs) with the goal of conducting gene therapy clinical trials for cancer treatment. The purpose of this RFA is to promote the design and implementation of clinical trials of gene therapy, to support the requisite preclinical studies establishing the scientific and technical basis for human studies, and to foster the development of interactions between basic scientists and clinical researchers necessary for bringing gene therapy to patient trials. The program project grant mechanism will support the establishment of broadly based, multi-disciplinary and multi-institutional research programs centered around this goal. For the purposes of this RFA, gene therapy will be defined as the transfer of a functioning gene(s) into somatic cells to treat disease.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Implementation Grants for Gene Therapy Programs in Cancer Treatment, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic non-profit and for-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications may be submitted from a single institution or may include arrangements with one or more additional institutions, if appropriate. Applications from minority individuals and women are encouraged. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Support of the program will be through the National Institutes of Health (NIH) program project research grant (P01). Responsibilities for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed four years. The anticipated award date will be September 30, 1992.

This RFA is a one-time solicitation. If the NCI determine that there is a sufficient continuing program need, the NCI will invite recipients of awards under this RFA to submit competitive continuation applications for review.

FUNDS AVAILABLE

Approximately \$5,000,000 in total costs per year for four years will be committed to fund applications submitted in response to this RFA. It is anticipated that six to eight awards will be made. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the continuing availability of funds for this purpose.

RESEARCH OBJECTIVES

The Cancer Therapy Evaluation Program is seeking applications for research program project grants (P01) to establish interactive GTPs with the goal of conducting gene therapy clinical trials for cancer treatment. The applications must be focused on a specific clinical therapeutic approach. These awards are envisioned to serve as "implementation grants" for the development of a collaborative effort between a multidisciplinary and, possibly, multi-institutional group of investigators to rapidly move forward new approaches in gene therapy of cancer into the clinic. Funds are to be used to conduct the necessary preclinical studies to prepare a clinical product or procedure for human trials and to gain regulatory approval to conduct such trials. The Cancer Therapy Evaluation Program will provide assistance in applying for regulatory approvals. The NCI is encouraging investigators to forge new collaborations with other research institutions and private industry to obtain the necessary expertise in all aspects of the research program.

Initial approaches to gene therapy would involve the alteration and administration of human somatic cells. Future techniques may include approaches such as the direct administration of genetic material to patients. Examples of gene therapy for the treatment of cancer include: (1) implantation of tumor cells transfected with functioning cytokine genes to elicit an immune response; (2) insertion of genes into host effector cells that will enhance their ability to recognize and bind tumor specifically and/or will potentiate the inflammatory response of the host at the site of tumor; (3) insertion of genes into normal cells of the host, such as bone marrow stem cells, that will increase their resistance to the toxic effects of chemotherapy; (4) in vivo introduction of genes into cancer cells that will restore suppressor gene function or neutralize the function of activated oncogenes that maintain the neoplastic phenotype. Investigators are not limited to the above studies; however, all studies must be therapeutic in intent and not solely diagnostic.

STUDY POPULATIONS

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit by April 3, 1992, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information is helpful in planning for the review of applications. It allows NCI staff to

estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is sent to:

Ms. Diane Bronzert
Program Director, Cancer Therapy Evaluation Program
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

APPLICATION PROCEDURES

Applications MUST be received by May 15, 1992. If an application is received after that date, it will be returned. The research grant application form PHS 398 (revised 10/88 or 9/91) must be used in applying for these grants. These forms are available at most institutional business offices; from the Office of Grant Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892, telephone 301/496-7441; and from the NCI Program Director named below. Copies of the "Guidelines for the Program Project Grant of the National Cancer Institute" (revised 1987) for the development of a program project grant application are available from the Program Director and from the NCI Referral Officer, Division of Extramural Activities, NCI, Room 848, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Questions concerning the relevance of proposed research to the RFA may be directed to program staff as described in the INQUIRIES section.

INQUIRIES

This is not the complete RFA. Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct inquiries regarding programmatic issues to Ms. Diane Bronzert at the address listed under LETTER OF INTENT.

Direct inquiries regarding fiscal matters to:

Ms. Marian Focke
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 242
Bethesda, MD 20892
Telephone: (301) 496-7800, extension 46
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No 93.395, Cancer Treatment Research. Awards are made under authorization of the Public Health Service Act, Title IV Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations at 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

QUANTITATION OF TUMOR RESPONSE TO TREATMENT: A THREE-DIMENSIONAL APPROACH

NIH GUIDE, Volume 21, Number 3, Part II of II, January 24, 1992

RFA AVAILABLE: CA-92-08

P.T. 34; K.W. 0715035, 0785140, 0706030

National Cancer Institute

Letter of Intent Receipt Date: April 21, 1992
Application Receipt Date: May 21, 1992

PURPOSE

The Radiation Research Program (RRP), Division of Cancer Treatment (DCT), of the National Cancer Institute (NCI), announces the availability of a Request for Applications (RFA) that advances current methods of imaging-based tumor volumetric analysis for optimization of response assessment in oncology. The objective of this RFA is to support meritorious research in the development of a three-dimensional (3D) approach to serial

quantitation of tumor volume. The proposed research is expected to improve clinical management in oncology and to facilitate the development and evaluation of anti-neoplastic drugs and other treatment modalities in cancer patients.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. This RFA, Quantitation of Tumor Response to Treatment: A Three Dimensional Approach, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit, public and private organizations, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health (NIH) individual research grant (R01). Applicants will be responsible for the planning, direction, and execution of the proposed project.

This RFA is a one-time solicitation. Generally, future unsolicited competitive continuation applications will compete as research project applications with all other investigator-initiated applications and be reviewed by the Division of Research Grants (DRG). If the NCI determines that there is a sufficient continuing program need, a request for competitive continuation applications will be announced.

FUNDS AVAILABLE

Approximately \$500,000 in total costs per year for three years will be committed to fund applications that are submitted in response to this RFA. It is anticipated that three awards will be made. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. The total project period for applications submitted in response to the present RFA may not exceed three years. The earliest feasible start date for the initial awards will be March 1, 1993. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH GOALS AND SCOPE

The specific goal of this initiative is the development and optimization of a quantitative analysis of tumor response to treatment based on 3D medical imaging. The proposed research will stimulate the achievement of optimal tumor volumetric analysis by means of the development of advanced approaches to two critical basic computer science topics, automated image segmentation and multimodality image registration, and their validation and testing.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 21, 1991, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is requested in order to provide an indication of the number and scope of applications to be reviewed.

The letter of intent is to be sent to:

Faina Shtern, M.D.
Chief, Diagnostic Imaging Research Branch
Radiation Research Program
National Cancer Institute
Executive Plaza North, Suite 800
Bethesda, MD 20892
Telephone: (301) 496-9531
FAX: (301) 480-5785

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 10/88, reprinted 9/89 or rev. 9/91) must be used in applying for these grants. These forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892, and from the NCI program director named below.

Applications must be received by May 21, 1992. If an application is received after that date, it will be returned.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed (initially) by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Those applications judged to be both competitive and responsive will be further evaluated according to the review criteria stated below for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NCI. The second level of review by the National Cancer Advisory Board considers the special needs of the Institute and the priorities of the National Cancer Program.

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of this RFA and requests for the RFA are to be directed to Dr. Faina Shtern at the above address. The Program Director welcomes the opportunity to clarify any issues or questions from potential applicants.

Direct inquiries regarding fiscal matters to:

Marian F. Focke
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 242
Bethesda, MD 20892
Telephone: (301) 496-7800, extension 46

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.395, Cancer Treatment Research. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

EVALUATION OF THE USE OF GUIDELINES IN LARGE GROUP PRACTICES

NIH GUIDE, Volume 21, Number 3, Part II of II, January 24, 1992

RFA AVAILABLE: HS-92-02

P.T. 34; K.W. 0730000, 0785035, 0715072, 0715115

Agency for Health Care Policy and Research

Application Receipt Date: March 24, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The Agency for Health Care Policy and Research (AHCPR) announces the availability of an RFA for cooperative agreements to demonstrate research methods for evaluation of alternative strategies for implementation of clinical practice guidelines and the effects of implementing practice guidelines on the delivery of primary care in large group practices. The specific clinical practice guidelines to be evaluated are: (1) those developed by the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure, and (2) the forthcoming guidelines for the detection and management of depressed patients in primary care settings, developed with the support of the AHCPR Forum on Quality and Effectiveness in Health Care.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Evaluation of the Use of Guidelines in Large Group Practices, is related to the priority areas of heart disease and stroke, mental health and mental health disorders, and clinical preventive services. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report:

ELIGIBILITY REQUIREMENTS

Applications may be submitted by non-profit entities, such as universities, hospitals, and clinics, State and local governments, and eligible agencies of the Federal government. Applications from minorities and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the cooperative agreement (U10) mechanism of support. Under the terms of the cooperative agreement, the awardee defines the details of the project within the guidelines of the RFA, retains primary responsibility for performance of the activity and for analyzing and publishing results, and agrees to accept assistance, close coordination, and participation of the designated program administrator in all aspects of the scientific and technical management of the project in accordance with this RFA and the terms of the award.

The total project period for applications submitted in response to the present RFA may not exceed three years. The anticipated award date will be August 1, 1992. This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary AHCPR peer review procedures.

FUNDS AVAILABLE

AHCPR expects to award a total of \$500,000 in FY 1992 for the support of up to three awards. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit and the availability of funds for this purpose.

RESEARCH OBJECTIVES

Patient outcomes research has several goals related to increasing the knowledge base to improve clinical decision-making. One mechanism is the development and dissemination of guidelines that will help physicians provide appropriate, cost-effective care. Assessing the extent to which practice guidelines can influence practitioner and patient behavior to facilitate the appropriate use of specific interventions, while discouraging inappropriate use, is important for translating the results of improved information to improving the quality of care.

Although several guidelines have been developed by professional organizations, insurers, utilization review panels and others, the most effective approaches for implementing guidelines to effect sustained change in behavior and improve the quality of care have not yet been determined. The development of practical strategies for implementing and evaluating clinical practice guidelines is prerequisite to ascertaining the effects of practice guidelines on the cost, quality and appropriateness of clinical services.

Traditionally, assessment of physician compliance with practice guidelines in health care has been based on the belief that quality is best achieved by discovering "bad" practices and taking corrective action. An alternative approach to improving the quality of medical services is based on the principles of continuous quality improvement (CQI). This model engages the support and participation of all members of the health care team in an effort to achieve continuous improvement in quality, defined to include the needs and preferences of the patient. CQI offers the potential of identifying multiple variables relevant to practitioner knowledge and behavior and the process of delivering care in practice settings. Preliminary reports of the use of CQI in developing and implementing clinical algorithms for a variety of clinical problems in a large group HMO setting indicate its promise as one method for implementing practice guidelines. Additional research is needed to compare a CQI approach with other methods and to test how effective this methodology is in other practice settings.

The overall goal of the desired research is to evaluate strategies for implementation of clinical practice guidelines and improve understanding of the process and effects of such implementation and incorporation of guidelines into practice. The proposed research is to be conducted in large group practices providing primary care. Studies must include an experimental or quasi-experimental design for evaluating at least two approaches for implementing the guidelines in group practice settings. One method must incorporate the principles of CQI; additional strategies based on relevant theories of practitioner and organizational behavior can be selected by the Principal Investigators.

Two sets of guidelines will be used. Hypertension guidelines are available currently from the JNC and will be updated in October 1992. Guidelines on the diagnosis and treatment of depressed outpatients in primary care settings are being developed with the support of AHCPR and will not be available before April 1, 1992. Therefore, applicants should design their study consistent with their knowledge of existing clinical recommendations for depression and the relevant literature.

The following illustrate possible research areas and questions related to the implementation of practice guidelines:

What are the effects of practice guidelines on practitioners' knowledge and behavior? How do providers evaluate new information and translate this information to their practices? Which mechanisms, e.g., incentives, penalties, administrative rules, are most effective in improving practitioner compliance with guidelines? How will practitioners revise or tailor established or newly developed guidelines to their individual patients?

What are the effects of guidelines on practice? What is the relative cost-effectiveness of various strategies to implement guidelines, in terms of additional personnel or administrative mechanisms required to improve compliance with guidelines? How do practitioners and organizations incorporate multiple sets of guidelines for the same or similar clinical problems? How do practitioners and patients incorporate practice guidelines in the context of unrelated concerns, e.g., reason for visit unrelated to the content of the specific guidelines? How do practitioners and patients prioritize among existing guidelines for multiple problems, i.e., is there a rationale for compliance with some guidelines and not others? What are the barriers to implementation of guidelines, and how can they be addressed? What are the barriers that prevent high-risk patients from receiving the recommended services? How can these barriers be modified or eliminated?

What is the effect on patient behavior, and ultimately on patient outcomes? What strategies can practitioners use to modify patients' health behaviors? What factors influence patients' acceptance of practice guidelines? In what ways do the guidelines conflict with patient expectations for service utilization?

SPECIAL REQUIREMENTS

The administrative and funding mechanism to be used to support these awards will be cooperative agreements (U10) between each awardee and the AHCPR. In a cooperative agreement there is substantial Federal programmatic involvement above and beyond the levels characteristic for traditional program management of grants. Prospective applicants are encouraged to obtain a copy of the RFA for additional information (see INQUIRIES section below).

SPECIAL INSTRUCTIONS TO APPLICANTS CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

The AHCPR observes NIH and ADAMHA policy requiring applicants to give special attention to the inclusion of minorities and women in study populations. If women or minorities are excluded or inadequately represented in research, a clear and compelling rationale should be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

Applications must be submitted on the PHS 398 (revised 10/88) application form that is available at most institutional business offices and from the Office of Scientific Review, AHCPR, 2101 East Jefferson Street, Rockville, MD 20852, telephone: 301-227-8449. State and local governments must use form PHS 5161.

The RFA contains further details regarding application procedures. Applications must be received by March 24, 1992.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by AHCPR staff for completeness and responsiveness. Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific/technical merit by a peer review group convened by the AHCPR. A second level of review will be provided by the National Advisory Council for Health Care Policy, Research and Evaluation.

In addition to the criteria generally used by AHCPR peer review groups to assess applications, the following review criteria will be used in evaluating applications received in response to this RFA:

- o adequacy of the plan for obtaining detailed medical record data evaluate relevant medical and nonmedical factors related to implementation of practice guidelines and patient outcomes following implementation;
- o qualifications and experience of the Principal Investigator and proposed staff, particularly as they relate to conducting research in quality improvement and quality assurance;
- o adequacy of the facilities and resources available to the grantee, particularly in making available practice sites that are already using a continuing quality improvement approach to quality improvement and have the ability to randomize patients and/or practitioners.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Paul A. Nutting, M.D., MSPH
Center for General Health Services Extramural Research
Agency for Health Care Policy and Research
Executive Office Center, Suite 502
2101 E. Jefferson St.
Rockville, MD 20852-4908
Telephone: (301)-227-8357

Direct inquiries regarding fiscal and administrative matters to:

Ralph Sloat
Chief, Grants Management Branch
Agency for Health Care Policy and Research
Executive Office Center, Suite 601
2101 E. Jefferson St.
Rockville, MD 20852-4908
Telephone: (301)-227-8447

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.226. Awards are made under authority of Title IX of the Public Health Service Act, as amended (42 USC 299), and administered under PHS grants policies and in accordance with program regulations (Title 42 CFR, Part 67, Subpart A). The requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs," are not applicable to AHCPR research grant programs.

CANCER PREVENTION AND CONTROL RESEARCH SMALL GRANT PROGRAM

NIH GUIDE, Volume 21, Number 3, Part II of II, January 24, 1992

RFA AVAILABLE: CA-92-04

P.T. 34; K.W. 0715035, 0795003, 0745027, 0745035, 0710095, 0404000

National Cancer Institute

Application Receipt Date: May 6, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) announces the availability of an RFA Cancer Prevention and Control Research Small Grant Program. This program is designed to aid and facilitate the growth of a nationwide cohort of scientists with a high level of research expertise in the field of human cancer control intervention research. New and experienced investigators in relevant fields and disciplines (e.g., disease prevention and control, medicine, public health, health promotion, epidemiology, social work, nursing research, nutrition, health policy, health services research, and behavioral sciences, such as social psychology, health education, sociology, and community organization) may apply for small grants to test ideas or do pilot studies.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Cancer Prevention and Control Research Small Grant Program, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Investigators are eligible to apply for a small grant to support research on a cancer control topic if they are interested in conducting exploratory studies in cancer control research. Eligible applicants include established researchers, new investigators, qualified staff of public health departments and collaborating agencies, and predoctoral investigators currently enrolled in an accredited doctoral degree program. Applications from minority individuals and women are encouraged. Non-profit and for-profit organizations and institutions, governments and their agencies, and occasionally individuals, are eligible to apply.

The only INELIGIBLE applicants are:

- o those individuals who are or have previously been a Principal Investigator on an NCI-funded CANCER CONTROL grant or contract for more than TWO years;
- o previous recipients (Principal Investigators) of a DCPC Small Grant;
- o foreign institutions.

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health (NIH) small grant (R03). Applicants will be responsible for planning, direction, and execution of the proposed project. The anticipated award date is March 1, 1993. This RFA is a one-time solicitation. Small grants are not renewable.

FUNDS AVAILABLE

Approximately \$500,000 in total costs for two years will be committed to fund applications that are submitted in response to this RFA. Direct costs maximum is \$50,000, and the duration of support is two years maximum. It is anticipated that up to seven awards will be made. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The Cancer Prevention and Control Research Small Grants Award is designed to encourage investigators from a variety of academic, scientific, and public health disciplines to apply their skills to scientific investigations in the field of human cancer control intervention research. The research may occur in a variety of settings, such as communities, schools, health departments, and work sites. These investigators will become part of the new nationwide group of scientists pursuing cancer control research goals.

RESEARCH APPROACHES

Within this small grant program, investigators may choose any of the full range of scientific approaches in their work. Many studies and research designs may contribute to the design, implementation or evaluation of future phase III-V studies, e.g., descriptive baseline surveys, testing, modification and validation of surveys or program materials for use in the proposed population groups, and testing of recruitment or compliance procedures for participants.

Investigators must address the specific aims and hypotheses, the background and significance of the proposed work, results of any preliminary studies, experimental design and methods including any relevant theoretical concepts that underlie the research, human subjects involvement and protection, and relevant literature (see instructions in the grant application).

PROGRAM AREAS OF INTEREST

Cancer Control program areas appropriate for HUMAN INTERVENTION research grant applications include:

- o Prevention (chemoprevention, diet and nutrition intervention studies)
- o Screening and early detection, e.g., pilot studies of new methods; application of the "NCI Guidelines For Early Detection". In the area of breast screening and detection, studies of breast self-examination as a single modality will not be accepted.
- o Cancer control sciences (studies to change current behaviors and/or institute new behaviors or health promotion interventions effective in reducing incidence, morbidity, or mortality from cancer)
- o Smoking prevention and cessation pilot studies targeted at improving utilization of current technologies in target populations or organizations are encouraged. Minor enhancements of existing technology are not encouraged.
- o Applications research in modifying, feasibility testing, and adopting proven, state-of-the-art intervention programs and strategies from other research projects (e.g., screening, smoking prevention) for use in special populations, State and local health agencies, or other organizational and community settings.

In addition, planning, epidemiologic, and survey studies aimed at developing cancer control operations research and evaluation studies are appropriate for human intervention research grant applications.

- o Community oncology (improving the application of patient management and continuing care research advances into community settings).
- o Applied epidemiology studies (using epidemiologic methods to determine the association between exposure to an INTERVENTION and its impact on disease) are acceptable within the above program areas.

ALTHOUGH THE SPECIFIC STUDY PROPOSED MAY ATTEMPT ONLY TO OBTAIN PRELIMINARY DATA AND/OR CONDUCT PILOT STUDIES IN SUPPORT OF A FUTURE, MORE DETAILED STUDY, IT IS IMPORTANT THAT A LONG-TERM HUMAN CANCER CONTROL HYPOTHESIS AND SUPPORTING SCIENTIFIC JUSTIFICATION BE PRESENTED.

EXCLUSIONS

Studies to determine the efficacy of chemotherapy, surgery, radiotherapy, and other primary treatment interventions are not considered cancer control research under this RFA. Other laboratory animal studies are not allowed.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations

for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 10/88 or 9/91) must be used in applying for these grants. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, Maryland 20892, telephone 301/496-7441; and from the NCI Program Director named below.

REVIEW CONSIDERATIONS

Applications will be evaluated subject to the following criteria:

- o The scientific/technical merit of the research, including originality, feasibility, adequacy of design, plans for analyses and evaluation of data, and soundness of the research plan.
- o The quality of the Principal Investigator's research training, intervention experience, and potential for contribution as an investigator in the field of cancer control intervention research.
- o The adequacy of resources and facilities, and the supportive nature of the research environment.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Sherry L. Mills, M.D., M.P.H.
Program Director, Prevention and Control Extramural Research Branch
Division of Cancer Prevention and Control
National Cancer Institute
Executive Plaza North, Room 320
Bethesda, MD 20892
Telephone: (301) 496-8520

Direct inquiries regarding fiscal matters to:

Katharine Schulze
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892

Telephone: (301) 496-7800 ext. 16

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NIAID INSTITUTIONAL TRAINING AWARDS FOR CLINICAL RESEARCH ON THE ACQUIRED IMMUNODEFICIENCY SYNDROME

NIH GUIDE, Volume 21, Number 3, Part II of II, January 24, 1992

RFA AVAILABLE: AI-92-04

P.T. 44; K.W. 0720005, 0715008, 0785035

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: February 28, 1992

Application Receipt Date: April 8, 1992

PURPOSE

The National Institute of Allergy and Infectious Diseases (NIAID) announces the availability of a Request for Applications (RFA), NIAID Institutional Training Awards for Clinical Research on AIDS. The purpose of this RFA is to solicit applications from established programs of excellence at institutions that are able to develop a clinical research program that provides training opportunities to outstanding new investigators who have shown an interest in, and commitment to, clinical research on Human Immunodeficiency Virus (HIV) disease and the acquired immunodeficiency syndrome (AIDS). This program will target a variety of disciplines that work with

patient clinical material or other clinical data in clinical research.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, NIAID Institutional Training Awards for Clinical Research on AIDS, is related to the priority area of HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Only domestic academic, non-profit, private and public institutions are eligible to apply for this award. Only U.S. citizens or, non-citizen nationals, and individuals admitted to the U.S. as Permanent Residents are eligible to become trainees. Minority individuals and women trainees are encouraged.

MECHANISM OF SUPPORT

Awards for this program will be made as Institutional National Research Service Awards (NRSA) (T32), and thus are subject to the eligibility and evaluation criteria developed for that award. Applicants should carefully review these criteria, a copy of which is available from the institution's Office of Sponsored Research and from the National Institutes of Health, Division of Research Grants, telephone (301) 496-7441.

The total project period for applications submitted in response to the RFA may not exceed five years. This RFA is a one-time solicitation. Future unsolicited competing continuations will compete with investigator-initiated applications and will be reviewed according to the customary NIH peer review procedures.

FUNDS AVAILABLE

The NIAID has set aside \$750,000 in total costs for the first year of this RFA. The number of awards will be influenced by the availability of funds, the overall scientific merit of the applications, and relevance to program goals. Awards pursuant to this RFA are contingent on the continuing availability of funds for this purpose.

RESEARCH OBJECTIVES

The goals of the NIAID Institutional Training Awards for Clinical Research on AIDS are to:

- o Increase the number of clinical researchers with a broad background in clinical research methodology working in the field of HIV disease.
- o Provide support to post-doctoral fellows, advanced graduate students, and physicians for training in disciplines that are directly relevant to clinical biomedical research on HIV disease.
- o Provide a training experience that integrates the range of disciplines necessary for the conduct of clinical research.
- o Provide a training experience in an environment committed to interdisciplinary collaboration among faculty/investigators active in the field of HIV research.

Programs must include a range of disciplines requisite for the development of research skills in clinical studies on HIV/AIDS. These include: epidemiology, surveillance, natural history and transmission studies, biostatistics, the theoretical fundamentals of clinical research design, protocol development, regulatory requirements, ethical considerations, clinical research execution, data collection, quality assurance, data management and analyses, clinical immunology, virology, microbiology, infectious diseases, molecular biology, pharmacology, biochemistry, scientific writing, and manuscript preparation.

SPECIAL REQUIREMENTS

The policy of the NIH and the NIAID is to promote broad and systematic efforts to recruit women and individuals from minority groups that are known to be under-represented in biomedical research as trainees. Applicants must provide a description of special plans to recruit individuals from these groups.

An annual progress report on the achievements of the clinical research program must be submitted. This report must include an update on the efforts and the success in recruiting under-represented minorities and women.

LETTER OF INTENT

Prospective applicants are asked to submit by February 28, 1992, a letter of intent that briefly describes the proposed training program, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains is helpful in planning for the review of applications. It allows

the NIAID staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Evelyn M. Rodriguez, M.D.
Division of AIDS
National Institute of Allergy and Infectious Diseases
Solar Building, Room 2A23
Bethesda, MD 20892
Telephone: (301) 496-6177

APPLICATION PROCEDURES

The deadline for receipt of applications is April 8, 1992. Applications received after this date will be returned without review.

The research grant application form PHS 398 (revised 10/88) must be used in applying. The application kit contains special instructions for preparing NRSA institutional fellowship award applications. The PHS 398 forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892, telephone (301) 496-7441.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to Dr. Rodriguez at the address listed under LETTER OF INTENT.

Direct inquiries regarding fiscal and policy matters to:

Ms. Jane Unsworth
Chief, AIDS Grants Management Section
Grants Management Branch
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C19
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7075

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.856 - Microbiology and Infectious Diseases Research, and No. 93.885 - Immunology, Allergic and Immunologic Diseases Research. Grants are awarded under the authority of the Public Health Service Act, Title IV, Section 487, and administered under the PHS grants policies and Federal Regulations, most specifically 42 CFR Part 66. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

NEUROLOGICAL MOTOR CONTROL AND MOTOR CONTROL DISORDERS: RESTITUTION OF FUNCTION

NIH GUIDE, Volume 21, Number 3, Part II of II, January 24, 1992

PA: PA-92-36

P.T. 34; K.W. 0715140, 1002030, 0710085, 0705070, 0710050, 0715213

National Institute of Neurological Disorders and Stroke

PURPOSE

The National Institute of Neurological Disorders and Stroke (NINDS), a component of the National Institutes of Health (NIH), invites research grant applications through this Program Announcement (PA) for support of research on neurological motor control, motor control disorders, and the restitution of function. Applications covering a broad range of activities in the neurological sciences from basic research to clinical research are encouraged. It is expected that regardless of approach, all studies will be focused on normal and abnormal performance of the nervous system in regard to motor control. This type of solicitation is issued to encourage investigator-initiated research projects in areas of special programmatic interest to the NINDS.

BACKGROUND

The NINDS is the principal NIH component for support of basic and clinical research on the prevention, diagnosis, treatment, and rehabilitation of neurological disorders. Disorders in motor control occur as

sequelae to many neurological and neuromuscular diseases and disorders. Understanding these disorders and approaches to restitution of function in patients with these disorders is difficult because many elements of the nervous system interact to produce motor control in healthy individuals. Motor control involves broad areas of the central nervous system including the spinal cord, the cerebellum, and motor areas of the cortex, basal ganglia, and thalamus among others. Sensory input is also an important element in motor control. In addition, it is being increasingly appreciated that nerve-muscle interactions and the intrinsic properties of muscles and tendons may play a significant role in motor control. The understanding of motor control necessary for appropriate treatment of its disorders requires a detailed understanding of the individual elements of motor control systems and, equally, an understanding of how the different components interact. This PA is issued to encourage grant applications that cover a broad range of motor disorders, areas of the nervous system, and levels of integration but that share the common focus of motor control and its disorders.

RESEARCH GOALS AND SCOPE

This announcement is issued to encourage and foster investigator-initiated basic, clinical, and applied research on motor control and its disorders. Examples of research objectives appropriate for inclusion in applications responsive to this PA include:

- o Studies of the neurophysiological foundation of motor control;
- o Studies of the biomechanics and neuromuscular physiology of motor control including conscious and automatic control in humans or animals;
- o Studies of the role of sensory systems in motor control;
- o Studies of the electrophysiological, neuroendocrine, and biochemical foundation of motor control;
- o Studies of the integration of motor, sensory, and central systems in gait, postural control, and fine motor control such as hand movements;
- o Studies of the neurological dysfunctions in motor control associated with cerebellar degeneration, hereditary ataxias, demyelinating disorders, such as multiple sclerosis, and in degenerative disorders such as Huntington's and Parkinson's disease;
- o Studies of abnormal nervous system functioning after viral infection, stroke, trauma, toxic insult, or in cerebral palsy and post-polio syndrome;
- o Physiologic analysis of basic movement disorder mechanisms and symptomatology, e.g., chorea, dystonia, rigidity, spasticity, and tremor;
- o Applied research directed at improving or restoring motor control in neurologically impaired individuals;
- o Studies of neurological locomotor abnormalities in AIDS, neuropathies, atrophies, and other neurological diseases.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Neurological Motor and Motor Control Disorders: Restitution of Function, is related to the priority area of chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

MECHANISM OF SUPPORT

The support mechanisms for this research will be the individual research grant (R01), the First Independent Research Support and Transition (FIRST) Award (R29), Research Career Development Award (K04), Clinical Investigator Award (K08), and the program project grant (P01). The number of awards to be made is dependent upon receipt of a sufficient number of applications of high scientific merit and upon availability of funds.

GENERAL REQUIREMENTS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size

appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerers are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaska Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURE

Applications must be submitted on the grant application form PHS 398 (Rev. 10/88, reprinted 9/89) and will be accepted on any of the three receipt dates for research grant applications, February 1, June 1, and October 1.

Application kits are available at most business and grants/contracts offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441.

On the first (face) page, item 2, of the application, the word "yes" must be checked and the title and number of the announcement typed in the space provided: NEUROLOGICAL MOTOR CONTROL AND MOTOR CONTROL DISORDERS: RESTITUTION OF FUNCTION, PA-92-36.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator must be included with the application.

The original and six copies of the application must be sent or delivered to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will receive institute and initial review group (IRG) assignment on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by an IRG. Following IRG review, the applications will receive a second-level review by an appropriate Council/Board. Applications will compete for available funds with all other approved applications assigned to the institute.

REVIEW CRITERIA

The standard review criteria will be used to assess the scientific merit of applications. The IRG will be reviewing the adequacy of protection of human subjects, the humane care of animals, and biosafety conditions. In clinical research studies, reviewers also will be evaluating the adequacy of the inclusion of women and minorities in the study populations.

STAFF CONTACT

Investigators are encouraged to contact:

Dr. William Heetderks
Division of Fundamental Neuroscience
National Institute of Neurological Disorders and Stroke
Federal Building, Room 916
Bethesda, MD 20892
Telephone: (301) 496-5745

Dr. A. P. Kerza-Kwiatecki
Division of Demyelinating, Atrophic, and Dementing Disorders
National Institute of Neurological Disorders and Stroke
Federal Building, Room 804
Bethesda, MD 20892
Telephone: (301) 496-1431

Dr. Floyd J. Brinley, Jr.
Division of Convulsive, Developmental, and Neuromuscular Disorders
National Institute of Neurological Disorders and Stroke
Federal Building, Room 816
Bethesda, MD 20892
Telephone: (301) 496-6541

Dr. Patricia A. Grady
Division of Stroke and Trauma
National Institute of Neurological Disorders and Stroke
Federal Building, Room 8A10
Bethesda, MD 20892
Telephone: (301) 496-4226

For fiscal and administrative matters contact:

Kathleen Howe
Grants Management Specialist
National Institute of Neurological Disorders and Stroke
Federal Building, Room 1004
7550 Wisconsin Ave.
Bethesda, MD 20892
Telephone: (301) 496-9231

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.854 - Biological Basis Research in Neurosciences, and 93.853 - Clinical Research related to Neurological Disorders. Grants will be awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or a Health Systems Agency review.

BIOMEDICAL RESEARCH SUPPORT SHARED INSTRUMENTATION GRANT

NIH GUIDE, Volume 21, Number 3, Part II of II, January 24, 1992

PA: PA-92-37

P.T. 34; K.W. 0735000, 0780000

National Center for Research Resources

Application Receipt Date: March 26, 1992

BACKGROUND

The National Center for Research Resources (NCRR) is continuing its competitive Biomedical Research Support (BRS) Shared Instrumentation Grant (SIG) Program initiated in Fiscal Year 1982. The program was established in recognition of the long-standing need in the biomedical research community to cope with rapid technological advances in instrumentation and the rapid rate of obsolescence of existing equipment. The objective of the program is to make available to institutions with a high concentration of Public Health Service (PHS)-supported biomedical investigators research instruments that can only be justified on a shared-use basis and for which meritorious research projects are described.

An eligible institution may submit more than one application for different instrumentation for the March 26, 1992, deadline. However, if multiple applications are submitted for similar instrumentation from one or more

eligible components of an institution, then documentation from a high administrative official must be provided, stating that the multiple applications are a coordinated institutional resource plan, not an unintended duplication.

RESEARCH GOALS AND SCOPE

This program is designed to meet the special problems of acquisition and updating of expensive shared-use instruments that are not generally available through other PHS mechanisms, such as the individual research project, program project and center grant programs, the Biomedical Research Technology Grant Program, or the BRS Grant Program. Applications for the development of new instrumentation will not be considered.

ELIGIBILITY

The BRS Shared Instrumentation Grant Program is a subprogram of the BRS Grant Program of the NCRR. Awards are made under the authority of the BRS program and are made to institutions only, not to individuals. Therefore, eligibility is limited to institutions that received a BRS grant award in FY 1991. Awards are contingent on the availability of funds.

MECHANISM OF SUPPORT

BRS Shared Instrumentation Grants (S10) provide support for expensive state-of-the-art instruments utilized in both basic and clinical research. Applications are limited to instruments that cost at least \$100,000 per instrument or system. The maximum award is \$400,000. Types of instrumentation supported include, but are not limited to, nuclear magnetic resonance systems, electron microscopes, mass spectrometers, protein sequencer/amino acid analyzers, and cell sorters. Support will not be provided for general purpose equipment or purely instructional equipment. Applications for "stand alone" computer systems will only be considered if the instrument is solely dedicated to the research needs of a broad community of PHS-supported investigators.

Awards will be made for the direct costs of the acquisition of new, or the updating of existing, research instruments. The institution must meet those costs (not covered in the purchase price) required to place the instrumentation in operational order as well as the maintenance, support personnel, and service costs associated with maximum utilization of the instrument. There is no upper limit on the cost of the instrument, but the maximum award is \$400,000. Grants will be awarded for a period of one year and are not renewable. Supplemental applications will not be accepted. The program does not provide indirect costs or support for construction or alterations and renovations. Cost sharing is not required. If the amount of funds requested does not cover the total cost of the instrument, the application must describe the proposed source(s) of funding for the balance of the cost of the instrument. Documentation of the availability of the remainder of the funding, signed by an appropriate institutional official, must be presented to NCRR prior to the issuance of an award. Requests for a multiple instruments purchase totalling over \$400,000 must specify and justify which instrument(s) should be supported within the \$400,000 ceiling.

Applicants proposing the direct purchase of an instrument that the institution has secured or is planning to secure via a leasing agreement are strongly encouraged to consult with the institutional sponsored projects office regarding applicable PHS policy prior to executing the leasing agreement. If the leasing agreement was executed more than one year prior to submission of the SIG application, the applicant must provide strong justification for the requested Federal funds. Further, the instrument must be considered state-of-the-art at the time of submission of the SIG application.

A major user group of three or more investigators must be identified. A minimum of three major users must have PHS peer-reviewed research support at the time of the award; 50 percent of these grants must have been awarded by the NIH. The application must show a clear need for the instrumentation by projects supported by multiple PHS research awards and demonstrate that these projects will require at least 75 percent of the total usage of the instrument. Major users can be individual researchers, or a group of investigators within the same department or from several departments at the applicant institution. PHS extramural awardees from other institutions may also be included.

If the major user group does not require total usage of the instrument, access to the instrument may be made available to other users upon the advice of the internal advisory committee. These users need not be PHS awardees, but priority must be given to PHS-supported scientists engaged in biomedical/behavioral research.

ADMINISTRATIVE ARRANGEMENTS

Each applicant institution must propose a Principal Investigator who will assume administrative/scientific oversight responsibility for the instrumentation requested. An internal advisory committee to assist in this responsibility must also be utilized. The Principal Investigator and the advisory group are responsible for the development of guidelines for shared use of the instrument, for preparation of all reports required by the NIH, for relocation of the instrument within the grantee institution if the major user group is significantly altered, and for continued support for the maximum utilization and maintenance of the instrument in the post-award period.

A plan must be proposed for the day-to-day management of the instrument including designation of a qualified individual to supervise the operation of the instrument and to provide technical expertise to the users. Specific plans for sharing arrangements and for monitoring the use of the instrument must be described.

If a grant award is made, a final progress report will be required that describes the use of the instrument, a list of all users, and the value of the instrumentation to the research of the major users and to the

institution as a whole. This report is due within 90 days following the end of the project period.

REVIEW PROCEDURES AND CRITERIA

Applications are reviewed by specially convened initial review groups of the Division of Research Grants (DRG) for scientific and technical merit and for program considerations by the National Advisory Research Resources Council (NARRC) of the NCRR. Approximately half of the applications will be reviewed at the September 1992 NARRC meeting and the remainder at the NARRC meeting in February 1993. Funding decisions on all applications received for the March 26, 1992, deadline will not be made until the program receives an appropriation for FY 1993. The Council date will not affect funding decisions. The earliest award date will be February 1993.

Criteria for review of applications include:

- o The extent to which an award for the specific instrument would meet the scientific needs and enhance the planned research endeavors of the major users by providing an instrument that is unavailable or to which availability is highly limited.
- o The availability and commitment of the appropriate technical expertise within the major user group or the institution for use of the instrumentation.
- o The adequacy of the organizational plan and the internal advisory committee for administration of the grant including sharing arrangements for use of the instrument.
- o The institutional commitment for continued support of the utilization and maintenance of the instrument.
- o The benefit of the proposed instrument to the overall research community it will serve.

APPLICATION PROCEDURES

Copies of a more detailed announcement are being mailed to Program Directors of BRS grants and to sponsored program offices at all institutions currently receiving BRS grants. Interested investigators must obtain the complete announcement prior to preparing an application.

Applications must be submitted on the grant application form PHS 398 (rev. 10/88, reprinted 9/89). Application kits are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441. The title and number of the announcement must be typed in Section 2 on the face page of the application.

Applications must be received by March 26, 1992. Applications received after this date will not be accepted for review in this competition and will be returned to the applicant. The original and four copies must be sent to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

If appendix material is submitted, five collated sets must be included with the application package. Identify each of the five sets with the name of the Principal Investigator and the project title. This material will not be routinely duplicated and will be used in a limited way by members of the initial review group.

Two copies of the application and one copy of any appendix material must also be addressed to:

Biomedical Research Support Program
National Center for Research Resources
National Institutes of Health
Westwood Building, Room 10A11
5333 Westbard Avenue
Bethesda, MD 20892

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Marjorie A. Tingle, Ph.D.
Director, Biomedical Research Support Program
National Center for Research Resources
Westwood Building, Room 10A11
Bethesda, MD 20892
Telephone: (301) 496-6743

Direct inquiries regarding fiscal matters to:

Ms. Mary V. Niemiec
Office of Grants and Contracts Management
National Center for Research Resources
Westwood Building, Room 849
Bethesda, MD 20892
Telephone: (301) 496-9840

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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.337, Biomedical Research Support. Awards will be made under authorization of the Public Health Service Act, Title III, Part A, (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ERRATUM

PREPARATION AND DELIVERY OF HOMOGENEOUS CERAMIDETRIHEXOSIDASE

NIH GUIDE, Volume 21, Number 3, Part II of II, January 24, 1992

RFP AVAILABLE: NIH-NINDS-92-03

P.T. 34; K.W. 0780005, 0760080, 0760013

National Institute of Neurological Disorders and Stroke

This erratum is to correct the notice of availability of RFP NIH-NINDS-92-03 that was published in the NIH Guide for Grants and Contracts on January 10, 1992, Vol. 21, No. 1. The following information is deleted: "At the time of proposal submission, the offeror's facilities shall meet Food and Drug Administration standards in accordance with the Current Good Manufacturing Practices. Non-compliance with the above requirement shall immediately render the proposal technically unacceptable without the consideration of other evaluation criteria." In lieu of the above, the following is incorporated: "The offeror's facilities shall meet Food and Drug Administration standards in accordance with the Current Good Manufacturing Practices at the time of submission of a Best and Final Offer."

This is not a Request for Proposals (RFP). To receive a copy of the RFP, submit a written request to the following address and supply two self-addressed mailing labels. All responsible sources shall be considered by the agency. The RFP will be issued on or about January 28, 1992 (revised) with proposals due on March 27, 1992 (revised).

Contracting Officer
Contracts Management Branch, DEA
National Institute of Neurological Disorders and Stroke, NIH
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892

Attention: RFP No. NIH-NINDS-92-03

ACADEMIC RESEARCH ENHANCEMENT AWARD

PA-92-28

P.T. 34; K.W. 0710030, 0404000, 1014006

National Institutes of Health

Application Receipt Date: June 19, 1992

This announcement, which was published in the NIH Guide for Grants and Contracts on January 10, 1992, Vol. 21, No. 1, contained an error in the application receipt date. The correct receipt date is June 19, 1992.

NIH GUIDE

For Grants and Contracts

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Bethesda, Maryland 20892

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21, No. 4
January 31, 1992

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REVISED PHS 398 APPLICATION FORM SOON TO BE AVAILABLE

NIH GUIDE, Volume 21, Number 4, January 31, 1992

P.T. 34; K.W. 1014006

Public Health Service

The newly revised Public Health Service grant application form -- Standard Form PHS 398 -- will be available for shipping to applicants and applicant organizations early in March 1992. This revision, dated 9/91 and approved through 6/30/94, replaces the current version that was revised 10/88 and approved through 3/31/91. Applicants are to use the new form starting with: the May 1, 1992, receipt date for AIDS applications; the May 10, 1992, receipt date for NRSA Institutional Training Grant applications; the June 1, 1992, receipt date for unsolicited research grant and Research Career Development Award (RCDA) applications; and the June 19, 1992, receipt date for the Academic Research Enhancement Award applications. Responses to requests for applications

with receipt dates after May 1, 1992, are to use the new form.

The revised PHS 398 form contains many significant changes and additions. Some of the more important changes are: a modest increase in the page limitations for the research plan and the introduction to revised applications; restrictions on appendix materials; an introductory section that describes the peer review process and includes contact telephone numbers for the awarding components of the Public Health Service; the requirement to list all of the personnel, not just the key personnel, on the abstract page; a detailed discussion of the various assurance and certification requirements; and an explanation of the required documentation regarding gender and minority representation in study populations.

To request two or more copies of the PHS 398 (revised 9/91), contact:

Administrative Services Office (PHS 398)
Division of Research Grants
National Institutes of Health
Westwood Building, Room 436
Bethesda, MD 20892

To request a single copy if the PHS 398 (revised 9/92), contact:

Office of Grants Inquiries (PHS 398)
Division of Research Grants
National Institutes of Health
Westwood Building, Room 449
Bethesda, MD 20892

To assist delivery, please include a completed mailing label for each box of 50 applications.

INQUIRIES

Direct questions regarding the use of the PHS 398 revised (9/91) to the program contact listed in the Program Announcement or Request for Applications or for unsolicited applications, or of the contacts listed in the revised PHS 398.

ANNUAL ASSURANCE UPDATE AND REPORT ON ACTIVITIES RELATED TO POSSIBLE MISCONDUCT IN SCIENCE

NIH GUIDE, Volume 21, Number 4, January 31, 1992

P.T. 34; K.W. 1014004, 1014006

Public Health Service

Effective Date: January 15, 1992

The Public Health Service (PHS) scientific misconduct regulation, 42 CFR 50 Subpart A, "Responsibilities of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science," requires each institution to make an annual report to the Office of Scientific Integrity (OSI) on the handling of allegations, inquiries and investigations into possible scientific misconduct in connection with research for which PHS funds have been requested or received and an annual update of the institutional assurance.

The official forms for the 1991 annual report were mailed by the OSI in October 1991 to the institutional official of each institution that filed an assurance with OSI for 1990-91. The completed form should have been returned to the OSI no later than January 15, 1992. OSI staff will review and use the form to update the PHS assurance files. An updated, active assurance is required for any institution to be eligible to apply for and/or receive PHS grants, fellowships, and cooperative agreements for research during calendar year 1992.

INQUIRIES

For further information, contact:

Dr. Alan Price or Ms. Carolyn Bowman
Office of Scientific Integrity
National Institutes of Health
Building 31, Room B1C39
Bethesda, MD 20892
Telephone: (301) 496-2624
Fax: (301) 402-0238

NCI BRIEFING ON "IMPLEMENTATION GRANTS FOR GENE THERAPY PROGRAMS IN CANCER TREATMENT"

NIH GUIDE, Volume 21, Number 4, January 31, 1992

RFA: CA-92-13

P.T. 34; K.W. 0715035, 0745032

National Cancer Institute

The notice of availability of a Request for Applications (RFA) for to invite program project grant applications

(P01) from interested investigators to establish interactive Gene Therapy Programs with the goal of conducting gene therapy clinical trials for cancer treatment was published in the NIH Guide for Grants and Contracts, Vol. 21, No. 3, Part II of II, January 24, 1992.

The National Cancer Institute (NCI) will hold a briefing session concerning this RFA on Friday, February 28, 1992 at the Holiday Inn Crowne Plaza in Rockville, Maryland. The briefing session will provide information on the regulatory process for obtaining approval to conduct gene therapy clinical trials. The briefing will begin at 8:30 a.m. and will adjourn by 4:00 p.m. There will be ample time for questions and answers. A summary of the proceedings of this meeting including questions and answers and copies of handouts, will be available upon request to Diane Bronzert.

All interested parties are invited to attend. Rooms for the night of February 27 are available for a special rate of \$89.00 plus tax. Reservations must be made directly to the Holiday Inn Crowne Plaza at (301) 468-1100. To receive the special rate, make the reservation by February 14 and mention the NCI Gene Therapy Programs meeting. For further information and to register for the meeting, contact:

Diane Bronzert, Program Director
Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

FUNDING STRATEGIES FOR FY 1992

NIH GUIDE, Volume 21, Number 4, January 31, 1992

P.T. 34; K.W. 1014006

National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration

The core principles described below will guide the Institutes/ Centers/Divisions (ICDs) in making funding decisions on Research Project Grants (RPGs) in FY 92.

Non-Competing RPGs

- o The award of non-competing grants at committed levels is the cornerstone of the National Institutes of Health (NIH) and Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Financial Management Plan and is the basis for credibility with the Congress and the scientific community.
- o The total costs of the cohort of non-competing grants, on the average, may not exceed 4 percent more than the prior budget period, taking into account one-time, non-recurring costs such as equipment. (ADAMHA noncompeting continuation awards will not come under this policy until FY 93).
- o Every effort will be made to accommodate shifts in the fiscal situation. If conditions are such that funding at the committed levels is not possible, the ICDs will obtain the approval of the Director, NIH, or the Administrator, ADAMHA, before taking any action to reduce the size of the non-competing awards.

Competing RPGs

- o The average costs of competing grants in one fiscal year will not increase by more than the Biomedical Research and Development Price Index over the average costs of competing grants in the previous fiscal year (including Small Business Innovation Research grants).
- o In making funding decisions, ICDs should consider the total costs of a grant, especially for applications with percentiles at the margin of the funding level.
- o An appropriate funding level for each award may be achieved by making budgetary reductions based on recommendations of the initial review group and advisory council/board, reviews by program and grants management staff for cost allowability and reasonableness, and, if necessary, programmatic adjustments. Programmatic adjustments may include reductions in investigator effort, adjustments of specific budget items, and/or decreases in the number of specific aims.
- o Award reductions of 25 percent or more below the level recommended by the initial review group on a single grant application may require a revised statement of specific aims and a revised budget from the Principal Investigator, properly countersigned by the institution, which must be reviewed and approved by the ICD program and grants management staff. Program staff, in consultation with the Principal Investigator and grants management staff, will decide if revised specific aims are required.
- o For competing continuation grants, one factor in arriving at the award amount will be the level of support in prior years and the extent to which the ICD can permit growth within the existing constraints on increases in average costs.
- o The average length of research project grants will not exceed four years (excluding Small Business Innovation Research grants).

Indirect Costs

The NIH and ADAMHA Financial Management Plans propose that, the effective indirect cost rate for competing and non-competing awards would become the ceiling rate for the remainder of the recommended period of support. Implementation of the ceiling on the rate of indirect costs is being deferred. However, the Department of Health and Human Services and the Office of Management and Budget, currently are considering this and other options for government-wide policies with respect to indirect costs.

This statement supersedes the previous informational footnotes on NIH Notices of Grant Award regarding this subject.

NATIONAL WORKSHOPS ON THE PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0783005

National Institutes of Health
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are sponsoring a series of workshops on the responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

SOUTH MIDWESTERN WORKSHOP

DATES: February 20 and 21, 1992

WORKSHOP SITE: San Antonio, TX

SPONSORS:

University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, TX 78284-7972

St. Mary's University
One Camino Santa Maria
San Antonio, TX 78228-8572

REGISTRATION CONTACT:

Ms. Angie Khan
Institutional Coordinator of Research Review
University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive (Room 402L)
San Antonio, TX 78284-7972
Telephone: (512) 567-2351

TOPIC: Identifying and Assessing Risks in Human Subject Research

SOUTHWEST WORKSHOP

DATES: March 24, 25, and 26, 1992

WORKSHOP SITE: Sheraton Old Town Hotel
800 Rio Grande Blvd., N.W.
Albuquerque, NM 87104

SPONSORS: University of New Mexico
Albuquerque, NM 87131-5126

Navajo Community College
Shiprock, NM 87420

REGISTRATION CONTACT:

University of New Mexico
Office of Continuing Medical Education
Health Sciences and Services Building (Room 140)
Box 713
Albuquerque, NM 87131-5126
Telephone: (505) 277-3942

TOPIC: Ethics, Justice, and Tribal Participation in Research with American Indians

NOTE: In conjunction with this Workshop, a session entitled, "Basic Training for IRB Members," will be held from 1:00 p.m. on March 24 until noon on March 25. During this session the Workshop participants will be divided into four IRBs that will review four different research protocols involving American Indians. The full conference will convene at 1:00 p.m. on March 25 and continue until 6:00 p.m. on March 26.

NORTHEASTERN WORKSHOP

DATES: April 27 and 28, 1992

WORKSHOP SITE: Philadelphia, PA

SPONSORS:

University of Pennsylvania
133 South 36th Street, Suite 300
Philadelphia, PA 19104-3246

Lincoln University
Lincoln University, PA 19352

REGISTRATION CONTACT:

Ms. Lynn Bevan
Assistant Director
Office of Research Administration
University of Pennsylvania
133 South 36th Street, Suite 300
Philadelphia, PA 19104-3246
Telephone: (215) 898-2614

TOPIC: The Shifting Ground: Current Issues for the Protection of Human Subjects on Biomedical and Behavioral Research

For further information regarding these workshops and future NIH/FDA National Protection of Human Subjects Workshops, please contact:

Ms. Darlene Marie Ross
Executive Assistant for Education
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
9000 Rockville Pike
Building 31, Room 5B59
Bethesda, MD 20892
Telephone: (301) 496-8101

NOTICES OF AVAILABILITY (RFPs AND RFAs)

SYNTHESIS AND TESTING OF MALE CONTRACEPTIVE AGENTS

NIH GUIDE, Volume 21, Number 4, January 31, 1992

RFP AVAILABLE: NICHD-CD-92-09

P.T. 34; K.W. 1003006, 1002012, 0750020

National Institute of Child Health and Human Development

The Contraceptive Development Branch of the Center for Population Research, National Institute of Child Health and Human Development, has a requirement for the synthesis and testing of male contraceptive agents. The specific objectives of the project are the design, synthesis, and testing of male contraceptive agents that inhibit testicular sperm development, post-testicular sperm maturation, and epididymal function.

Organizations must have adequate facilities and capabilities to carry out the proposed synthetic chemical capabilities to carry out the proposed synthetic chemical program. Specifically excluded from this project are LHRH analogs, gossypol derivatives, sex steroids, cytotoxic agents, and all alkylating agents including chlorohydrin, deoxyhalosugars, nitrogen mustards, ethyleneimines, and sulfonylalkanes. Non-specific antimetabolites, antimitotic agents, N-Substituted diamines (such as WIN. 13,099), most major classes of antibiotics, including the macrolides, aminoglycosides, penicillins, tetracyclines, sulfasalazine, and co-trimoxazole, and nitroheterocyclic compounds are also excluded. Proposals to merely collect compounds from various sources and/or only perform biological assays will not be considered.

It is anticipated that four contract awards will be made for a maximum period of three years each.

This announcement is not a Request for Proposals (RFP). The RFP will be issued on or about February 3, 1992. Proposals will be due approximately 90 days thereafter. Requests for copies of the RFP may be directed to:

Paul J. Duska, Contracting Officer
Contracts Management Branch, OGC
National Institute of Child Health and Human Development
Executive Plaza North, Room 610
900 Rockville Pike
Bethesda, MD 20892
FAX: (301) 402-0915

MICROSTIMULATION OF THE SACRAL SPINAL CORD - MAPPING

NIH GUIDE, Volume 21, Number 4, January 31, 1992

RFP AVAILABLE: NIH-NINDS-92-14

P.T. 34; K.W. 0745047, 0740050

National Institute of Neurological Disorders and Stroke

The Neural Prostheses Program of the National Institute of Neurological Disorders and Stroke, National Institutes of Health, is developing aids for the neurologically handicapped. These aids, known as neural prostheses, replace or supplement neurological function by directly interfacing with the nervous system. One means of accomplishing this is by microstimulation with microelectrodes implanted directly into neural tissue. Animal studies have shown the potential value of microstimulation with respect to increased stimulus selectivity. The principal goal of the proposed project is to investigate the feasibility of microstimulation of the sacral spinal cord as a method of controlling micturition and other somatic and autonomic functions. A research team with experience in neuroanatomical tracing, electrophysiology, and genito-urinary physiology will be required to successfully conduct this research. It is anticipated that one award will be made for a period of three years in September 1992.

This is not a Request for Proposals (RFP). To receive a copy of the RFP, submit a written request to the following address and supply two self-addressed mailing labels. All responsible sources shall be considered by the agency. The RFP will be issued on or about February 3, 1992, with proposals due on April 3, 1992.

Contracting Officer

Contracts Management Branch, DEA

National Institute of Neurological Disorders and Stroke

Federal Building, Room 901

7550 Wisconsin Avenue

Bethesda, MD 20892

Attention: RFP No. NIH-NINDS-92-14

MICRONACHINED STIMULATING ELECTRODES

NIH GUIDE, Volume 21, Number 4, January 31, 1992

RFP AVAILABLE: NIH-NINDS-92-13

P.T. 34; K.W. 0745047, 0706000

National Institute of Neurological Disorders and Stroke

The Neural Prostheses Program of the National Institute of Neurological Disorders and Stroke, National Institutes of Health, is seeking a contract to design and fabricate arrays of multielectrode stimulating probes capable of independently stimulating multiple small populations of neurons within the central nervous system. This project will involve research and development on micromachined, two and three dimensional thin-film electrode arrays capable of independently stimulating clusters of cells in the central nervous system. These electrodes will be designed to provide intracortical microstimulation at multiple sites in the visual cortex. The techniques developed will also be applicable to spinal cord microstimulating electrodes needed for future bladder and motor prostheses. It is anticipated that one award will be made for a period of three years in September 1992.

This is not a Request for Proposals (RFP). To receive a copy of the RFP, submit a written request to the address indicated below and supply two self-addressed mailing labels. All responsible sources shall be considered by the agency. The RFP will be issued on or about January 24, 1992, with proposals due on or about March 23, 1992.

Contracting Officer

Contracts Management Branch, DEA

National Institute of Neurological Disorders and Stroke

Federal Building, Room 901

7550 Wisconsin Avenue

Bethesda, MD 20892

Attention: RFP No. NIH-NINDS-92-13

TREATMENT OF RAYNAUD'S SYNDROME - CLINICAL UNITS

NIH GUIDE, Volume 21, Number 4, January 31, 1992

RFP AVAILABLE: NHLBI-HC-92-03

P.T. 34; K.W. 0715040, 0755015, 0740013

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) requires six clinical units to conduct a randomized

clinical trial of pharmacological and non-pharmacological treatments for Raynaud's syndrome. The primary goals of the study are to determine the best therapies for primary Raynaud's syndrome, particularly regarding the efficacy and duration of benefit from a course of temperature biofeedback treatment. Additionally, the study will evaluate the efficacy of the biofeedback approach in pre-sclerodermal Raynaud's and establish new information with respect to the role of emotional reactivity in the onset of symptoms. The study population for the Raynaud's Treatment Study will consist of approximately 480 patients recruited from six participating clinical units.

The period of performance is anticipated to begin September 30, 1992 through March 31, 1996.

The Request for Proposals (RFP) NHLBI-HC-92-03 will be available on or about January 28, 1992, with proposals due April 17, 1992. Six awards are anticipated to be made during September 1992. Written requests for the RFP must include three mailing labels, self-addressed, and must cite RFP No. NHLBI-HC-92-03.

Requests for copies of the RFP are to be sent to:

William M. Stevens
Contract Specialist for ECA Contracts Section
National Heart, Lung, and Blood Institute
Federal Building, Room 3C16
Bethesda, MD 20892

CLINICAL TRIAL OF AN IMPLANTABLE CARDIAC DEFIBRILLATOR

NIH GUIDE, Volume 21, Number 4, January 31, 1992

RFP AVAILABLE: NHLBI-HC-92-10

P.T. 34; K.W. 0740035, 0755015

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) requires one institution to conduct a multicenter trial to assess whether or not the use of an implantable cardiac defibrillator will result in reduced total mortality in comparison to conventional pharmacologic therapy in patients who have been resuscitated from sudden cardiac death or are otherwise at very high risk of mortality from arrhythmic causes. The study will consist of a pilot phase and a full-scale trial. Two hundred patients will be entered into the pilot study. If the pilot study demonstrates that a full-scale trial is feasible, approximately 1,000 patients will be entered into the full-scale study.

The period of performance is anticipated for 89 months beginning in September 1992.

This is a notice of availability of a Request for Proposals (RFP). RFP NHLBI-HC-92-10 will be available on or about January 28, 1992, with proposals due April 4, 1992. One award is anticipated by the Government. Only North American offeror institutions will be considered. Written requests for the RFP must include three mailing labels, self-addressed, and must cite RFP NHLBI-HC-92-10.

Requests for copies of the RFP are to be sent to:

Cheryl A. Jennings
Contracting Officer for ECA Contracts Section
National Heart, Lung, and Blood Institute
Federal Building, Room 3C16
Bethesda, MD 20892

EXTRAMURAL RESEARCH FACILITIES CONSTRUCTION PROJECTS

NIH GUIDE, Volume 21, Number 4, January 31, 1992

RFA AVAILABLE: OD-92-02

P.T. 02; K.W. 0715008, 0715035, 0715040, 1002046, 0735000

National Institutes of Health

Letter of Intent Receipt Date: March 10, 1992

Application Receipt Date: April 27, 1992

The Request for Applications (RFA) announced in this notice contains essential information for the preparation of an application. Potential applicants may obtain the RFA from the contact named in INQUIRIES, below.

PURPOSE

Public Law Number 102-170, the Appropriations Act for the Department of Health and Human Services for Fiscal Year 1992, provides \$7,500,000 in the budget of the Office of the Director, National Institutes of Health (NIH) for extramural facilities construction grants, to be awarded competitively. The NIH announces the availability of an RFA for the construction of facilities of urgent National importance for biomedical research and/or services to support such research.

The main objective of this construction program is to facilitate the conduct of biomedical research by providing funds for construction of new facilities and for the purchase of associated fixed research equipment essential for the operation of these facilities. Support may be requested for the construction of new facilities and additions or renovations to existing facilities to meet the biomedical research and/or biomedical research support needs of an institution or of a research group at that institution or elsewhere that utilizes the resources of that institution. The purpose of the proposed facility must be within the scope of one of the statutes authorizing the awards. Those statutes authorize construction grants that would benefit the fields of cancer, vision, heart, lung, blood, and AIDS research.

ELIGIBILITY REQUIREMENTS

Domestic, non-Federal, public and private non-profit institutions, organizations, and associations that conduct or support biomedical research are eligible to apply.

MECHANISM OF SUPPORT

The award mechanism will be the construction grant award (C06). Awards will be administered under Federal Regulation 45 CFR Part 74 - Administration of Grants, and for cancer construction projects, 42 CFR Part 52b.

FUNDS AVAILABLE

This one-time solicitation based on the Fiscal Year 1992 appropriation provides \$7,500,000 for this initiative. It is anticipated that four to five awards will be made. Up to 50 percent of the allowable costs of a project may be awarded, not to exceed \$2,000,000. Prior to grant award, the applicant must provide an assurance of required matching funds and that additional funds will be secured to meet any projected costs in excess of the award amount. Requests of less than \$500,000 will not be accepted. No indirect costs or continuation costs will be awarded.

LETTER OF INTENT

Prospective applicants are asked to submit by March 10, 1992, a letter of intent to the individual noted below. The letter, requested for planning purposes only, is to include the RFA number noted above, the name of the Principal Investigator, and a brief title of the type(s) of research/research support to be conducted in the new facility. The letter of intent does not commit the sender to submit an application, nor is it a prerequisite for submission of an application. The letter of intent is to be addressed to:

Mr. Kenneth Brow
Chief, Research Facilities Branch
Division of Cancer Biology, Diagnosis, and Centers
National Cancer Institute
Executive Plaza North, Room 300
Bethesda, MD 20892
Telephone: (301) 496-8534

APPLICATION PROCEDURES

Applicants must use Standard Form 424, "Application for Federal Assistance." Application forms and special instructions for completing the forms relevant to this RFA must be requested from the staff contact official noted below.

REVIEW CONSIDERATIONS

Applications that are complete and responsive will be reviewed for scientific and technical merit by appropriate special peer review group(s) that will be convened by the Division of Research Grants, NIH. The second level of peer review will be conducted by the National Advisory Board or Council appropriate for the statutory authority that is applicable to the application. Detailed criteria on which the applications will be evaluated are discussed in detail in the RFA.

INQUIRIES

For additional information, a copy of the RFA and application Standard Form 424 materials, contact:

Mr. Kenneth Brow
Chief, Research Facilities Branch
Division of Cancer Biology, Diagnosis, and Centers
National Cancer Institute
Executive Plaza North, Room 300
Bethesda, MD 20892
Telephone: (301) 496-8534

The programmatic and fiscal contacts are listed in the RFA.

AUTHORITY AND REGULATIONS

Grants for research facilities construction programs of the National Institutes of Health are subject to Executive Order 12372. Awards will be made under the construction grants authorities in the Public Health Service Act, Title IV, Sections 413(b)(6)(B), 421(b)(2)(B), 455, and 2351(a)(7)(B) and administered under PHS grants policies and Federal Regulations 45 CFR Part 74 and 42 CFR Part 52b for cancer construction only. This program is described in the Catalog of Federal Domestic Assistance, Number 93.392, Cancer-Construction.

ORTHOTICS AND PROSTHETICS RESEARCH

NIH GUIDE, Volume 21, Number 4, January 31, 1992

RFA AVAILABLE: HD-92-08

P.T. 34; K.W. 0415003, 0740070, 0710020, 1004015, 0710030

National Institute of Child Health and Human Development (NICHD)

Application Receipt Date: May 26, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The National Center for Medical Rehabilitation Research (NCMRR) of the National Institute of Child Health and Human Development (NICHD) invites research grant applications (R01) to develop new knowledge in the area of orthotic devices and internal and external prosthetic devices. Basic, clinical, and applied research applications that examine the development and improvement of orthotic and prosthetic devices are of high priority. Interdisciplinary, collaborative projects between specialists in physical and rehabilitation medicine (physiatry), basic and social scientists, and biomedical engineering are encouraged to apply improved understanding of human functioning and behavior to development and improvement of rehabilitation devices.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention goals of "Healthy People 2000," a PHS-led national activity for setting priorities. This RFA, Orthotics and Prosthetics Research, is related to the priority areas of nutrition, physical activity and fitness, heart disease and stroke, cancer, and diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: No. 017-001-474-0, or Summary Report: Stock No 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone: 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by public and private non-profit and for-profit organizations such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Project support may be requested for one to five years and may be renewed according to the conventional procedures that pertain to PHS grants. The earliest anticipated award date will be September 1992.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary NIH peer review procedures.

FUNDS AVAILABLE

Applications submitted in response to this announcement will compete for approximately \$1,000,000 in grant money that has been made available for this purpose in Fiscal Year 1992. This is a one-time announcement. The NICHD expects to award approximately five to seven grants. The number of awards depends upon the scientific merit of the applications, the degree of relevance to the stated goal of the announcement and the availability of funds.

RESEARCH OBJECTIVES

This RFA invites scientists to submit grant applications for research on the development and improvement of prosthetics and orthotics. Research in the areas of biomechanics, ergonomics, and engineering design has been impeded by gaps in knowledge. Applicants must propose investigations that employ interdisciplinary tactics for conducting research with the goals of maximizing function, comfort and support, minimal weight, cost effectiveness, and the highest degree of replication of natural function possible. Specific topics cited below are examples and should not be considered exhaustive of the potential types of research questions on orthotics and prosthetics that could be supported under this RFA.

- o Biomaterials - development of new composite materials for prosthetics and orthotics
- o Energy consumption and prosthetic use - physiological costs of ambulation
- o Gait changes with different prosthetic devices - optimal mobility using device
- o Prosthetic and orthotic device design development for different functions - new functions for different settings
- o Biomechanics of prosthetic attachment to limbs - simulation of normal motion

- o Tissue properties under physiological loads - in situ evaluation of tissue properties
- o Methods of powering prosthetic devices - myoelectric, mechanically powered devices
- o Computers in the design and manufacture of prosthetic devices - dynamic CAD
- o Sensory feedback systems which are adaptable to prosthetic and orthotic devices - improvement in tactile, proprioceptive, and pressure sense
- o Impact of surgery as related to orthotics and prosthetics
- o Effects of long-term use of orthotics and prosthetics

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a special justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

Applicants are to use form PHS 398 (rev. 9/91). This application form is available in the business or grants and contracts office at most academic and research institutions and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441. The receipt deadline for applications prepared in response to this RFA is May 26, 1992. Late applications will be returned to the applicant without review.

REVIEW CONSIDERATIONS

Applications will be reviewed by NICHD staff for responsiveness to the RFA. Applications deemed non-responsive will be returned to the applicant. In the event that an application is returned, the applicant has the option to resubmit the application to the Division of Research Grants as an unsolicited application during one of the three yearly review cycles (February 1, June 1, and October 1). If the application submitted in response to this RFA is substantially similar to a grant application already submitted to the NIH for review, but has not yet been reviewed, the applicant will be asked to withdraw either the pending application or the new one. Simultaneous submission of identical applications will not be allowed, nor will essentially identical applications be reviewed by different review committees. Therefore, an application cannot be submitted in response to this RFA that is essentially identical to one that has already been reviewed. This does not preclude the submission of the substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

Responsive applications may be evaluated by preliminary triage in a peer review group to determine scientific merit relative to other applications received in response to this RFA. Those applications judged to be non-competitive will be withdrawn and the applicant and the institutional business official will be notified. Those applications judged to be competitive will be further evaluated for technical and scientific merit by a review panel convened for this purpose by the Division of Scientific Review, NICHD.

Review criteria will be those used by the PHS to evaluate investigator-initiated R01 applications.

Following the initial review by study section, applications will be reviewed by the NICHD National Advisory Council.

INQUIRIES

Written and telephone requests for the RFA may be addressed to:

Louis A. Quatrano, Ph.D.
Chief, Applied Rehabilitation Medicine Research Branch
National Center for Medical Rehabilitation Research
National Institute of Child Health and Human Development
Executive Plaza South, Room 450W
6120 Executive Boulevard
Rockville, MD 20852
Telephone: (301) 402-2242

For fiscal and administrative inquiries regarding this announcement, potential applicants may write or call:

E. Douglas Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 501
6130 Executive Boulevard
Rockville, MD 20892
Telephone: (301) 496-1303

AUTHORITY AND REGULATION

This program is described in the Catalog of Federal Domestic Assistance No. 93.929-Medical Rehabilitation Research. Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ERRATUM

NIH LIBRARY



EVALUATION OF IMMUNE-BASED THERAPIES FOR AIDS USING ANIMAL MODELS

NIH GUIDE, Volume 21, Number 4, January 31, 1992

RFP AVAILABLE: NIH-NIAID-DAIDS-92-15

P.T. 34; K.W. 0745045, 0715008, 0755020

National Institute of Allergy and Infectious Diseases

The notice of availability of this Request for Proposals (RFP) was published in the NIH Guide for Grants and Contracts on January 17, 1992, Vol. 21, No. 2. This requirement has been amended to DELETE Part B entitled: Evaluation of Multipotent Stem Cell Reconstitution as a Therapy to Restore Immune Cell Deficits, and now consists only of: Evaluation of Immune-Based Therapies for AIDS Using Animal Models. This will provide for the evaluation of immune-based therapies in an established small animal model.

Requests for the RFP shall be directed in writing to:

Cyndie Cotter
Contract Management Branch
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3C-07,
6003 Executive Boulevard
Bethesda, MD 20892

To receive a copy of the RFP, supply this office with two self-addressed labels.

All responsible sources may submit a proposal that will be considered.

This announcement does not commit the Government to award a contract.

NIH GUIDE

For Grants and Contracts

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Bethesda, Maryland 20892

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21, No. 5
February 7, 1992

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NIH GUIDE, Volume 21, Number 5, February 7, 1992

P.T. 34; K.W. 1014002, 1014006

National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration

The PHS 398 (rev. 10/88) and PHS 2590 (rev. 10/88) grant application forms include a section on OTHER SUPPORT, where applicants are expected to list all, including both Federal and non-Federal, active support and pending and planned requests for support of research and research-related activities by all key personnel listed for each application. This information is important to PHS review-award processes to help evaluate the compatibility of application requests with investigators' capabilities and responsibilities, and eliminate unwarranted duplication of support for investigators' efforts. Application instructions emphasize the requirement for complete, accurate, and reliable information. In signing the face page of the application the principal investigator/program director and the applicant institution official certify that the application information is accurate and complete.

Applicants are reminded of the necessity to provide the full and reliable information requested. As noted in the instructions, "Incomplete, inaccurate, or ambiguous information about OTHER SUPPORT could lead to delays in review of the application." Further, applicants should be cognizant that serious consequences could result if failure to provide complete and accurate information be construed as an attempt to mislead PHS agency advisory groups and staff in their review and award responsibilities.

"OTHER SUPPORT" IN NIH AND ADAMHA R&D CONTRACT PROPOSALS

NIH GUIDE, Volume 21, Number 5, February 7, 1992

P.T. 34; K.W. 1014002, 1014006

National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration

Documentation required in National Institutes of Health and Alcohol, Drug Abuse, and Mental Health Administration uniform Request for Proposals include Standard Form 1411, Contract Pricing Proposal Cover Sheet, which instructs offerors to identify any contracts or subcontracts they have been awarded "for the same or similar items" within the past three years. Additionally, offerors are required to provide a Summary of Related Activities, identifying all active federal contracts, cooperative agreements, grants, and commercial agreements, and submitted proposals, including actual and proposed levels of effort for all key individuals in the proposal to NIH.

As with PHS grant applications, mentioned just above, offerors should be aware that serious consequences could result if their failure to provide complete and accurate information be construed as an attempt to mislead agency advisory groups and staff in their review and award responsibilities.

NATIONAL WORKSHOPS ON THE PROTECTION OF HUMAN SUBJECTS

NIH GUIDE, Volume 21, Number 5, February 7, 1992

P.T. 42; K.W. 0783005

National Institutes of Health
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are sponsoring a series of workshops on the responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

SOUTH MIDWESTERN WORKSHOP

DATES: February 20 and 21, 1992

WORKSHOP SITE: San Antonio, TX

SPONSORS:

University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, TX 78284-7972

St. Mary's University
One Camino Santa Maria
San Antonio, TX 78228-8572

REGISTRATION CONTACT:

Ms. Angie Khan
Institutional Coordinator of Research Review
University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive (Room 402L)
San Antonio, TX 78284-7972
Telephone: (512) 567-2351

TOPIC: Identifying and Assessing Risks in Human Subject Research

For further information regarding these workshops and future NIH/FDA National Protection of Human Subjects Workshops, please contact:

Ms. Darlene Marie Ross
Executive Assistant for Education
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
9000 Rockville Pike
Building 31, Room 5B59
Bethesda, MD 20892
Telephone: (301) 496-8101

NOTICES OF AVAILABILITY (RFPs AND RFAs)

MICROSTIMULATION OF THE SACRAL SPINAL CORD - CHRONIC STIMULATION

NIH GUIDE, Volume 21, Number 5, February 7, 1992

RFP AVAILABLE: NIH-NINDS-92-15

P.T. 34; K.W. 0745047, 0740050, 1002030

National Institute of Neurological Disorders and Stroke

The Neural Prosthesis Program of the National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health, is seeking a contractor to develop a method of chronic microstimulation of the sacral spinal cord and to evaluate its effects on neural and surrounding tissue in non-human animals. Information from spinal cord microstimulation studies is especially needed by designers of neural prostheses for paraplegic individuals who have sustained injuries to the spinal cord above the sacral region. Before microstimulation of the spinal cord can be evaluated in humans, a suitable chronic microstimulating electrode must be developed and its safety and effectiveness demonstrated in animals. A research team with experience in electrophysiology, microelectrode fabrication, and histopathological examination of neural tissue will be required to successfully conduct this research. It is anticipated that one award will be made for a period of three years in September 1992.

This is not a Request for Proposals (RFP). To receive a copy of the RFP, submit a written request to the following address, and supply this office with two self-addressed mailing labels. The RFP will be issued on or about February 7, 1992, with proposals due on April 6, 1992. All responsible sources shall be considered by the agency.

Contracting Officer
Contracts Management Branch, DEA
National Institute of Neurological Disorders and Stroke, NIH
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892

Attention: RFP No. NIH-NINDS-92-15

ONGOING PROGRAM ANNOUNCEMENTS

BIOMEDICAL RESEARCH SUPPORT GRANT

NIH GUIDE, Volume 21, Number 5, February 7, 1992

PA NUMBER: PA-92-38

P.T. 34; K.W. 0710030, 1014006

National Center for Research Resources

Application Receipt Date: June 15, 1992

PURPOSE

The National Center for Research Resources announces the Biomedical Research Support Grant (BRSG) Program for Fiscal Year (FY) 1992. Because the FY 1992 appropriation of \$5,204,000 for the BRSG Program is a significant reduction in the amount of funds available, awards which will be made on a competitive basis and fewer awards will be made.

The objectives of the BRSG Program for FY 1992 have been narrowed to focus on support for biomedical research projects in ways that are not adequately or efficiently provided for by other funding mechanisms such as the traditional investigator-initiated research project grant.

The allowable uses of BRSG funds for FY 1992 are:

- o Pilot research. Small, short-term projects that explore new research ideas (including multidisciplinary collaborations to explore new directions in biomedical research), seek preliminary findings, and establish the validity of the approach and pilot data that may provide the basis for research project grant applications.
- o New investigators. Initial research support for new investigators and investigators who have recently relocated and are in the process of applying for longer-term funding.
- o Unexpected requirements and opportunities for projects supported by other NIH funding mechanisms. This includes funding to enable research programs to continue during temporary lapses in project grant support.

These uses exploit the capacity of the BRSG to respond promptly to short-term, low-cost needs that are essential to complement research project grant mechanisms that typically fund continuing, multi-year programs.

ELIGIBILITY REQUIREMENTS

Institutions eligible to apply must have received a minimum of three allowable Public Health Service (PHS) research grants and/or cooperative agreements, totalling \$200,000 (including direct and indirect costs), awarded by the PHS during FY 1991. The guidelines which are available from the office listed under INQUIRIES describes the types of research grants that are allowable. The types of institutions eligible to apply remain unchanged, i.e., Health profession schools, graduate schools, hospitals, research organizations, and health departments. [If applicants are not selected for a BRSG award, they will remain eligible for the Shared Instrumentation Grant (SIG) and the Minority High School Student Research Apprentice Program (MHSSRAP).]

MECHANISM OF SUPPORT

The grant mechanism used for this program will be the S07 grant. Awards of \$50,000 for direct costs will be made for a twelve-month project period. No indirect costs will be provided. Final funding decisions will depend on the availability of funds. All awards will be made on or before September 30, 1992.

Because of the delay in the FY 1992 BRSG award process, the NCRR plans to extend the ending date of all active FY 1991 BRSG awards through September 29, 1992. Revised awards reflecting this extension will reach the institutions prior to the current March 31 end date of the FY 1991 award period.

RESEARCH OBJECTIVES

The BRSG Program complements the support of biomedical and behavioral research conducted through research project grants. The program thus enhances the productivity and cost-effectiveness of potential and existing PHS research project grants.

APPLICATION PROCEDURES

Letters of instructions and modified guidelines providing more specific information are being sent to Program Directors and institutional officials at institutions that, according to NIH records, received the required amount of funds from PHS grants in FY 1991. The narrative portion of applications will be limited to two to three pages in length and must address the items raised in the Review Procedures and Award Criteria sections. The receipt date for applications is June 15, 1992. Applications received after that date will be returned to the applicant.

REVIEW PROCEDURES

The NIH will conduct an administrative review, which is not intended to replace or duplicate on-site scientific and technical review of research application that will take into consideration the following criteria:

- o The role of the institutional BRSG Advisory Committee and the quality of the local peer review mechanisms in evaluating the scientific and technical merit of the proposed projects.
- o Overall appropriateness and potential of the proposed portfolio to improve the quality and maximize the benefits, cost effectiveness, and productivity of planned or ongoing PHS research project grants.
- o Accomplishments achieved with BRSG funds over the last three fiscal years.
- o Level of institutional commitment as indicated by matching contributions toward the proposed FY 1992 BRSG activities.

The second level review will be by the National Advisory Research Resources Council.

AWARD CRITERIA

Applications will compete for available funds with all other BRSG applications received for the June receipt date. Funding decisions will be based on:

- o Merit of the overall plan as determined by administrative review.
- o Program balance: awards will be distributed equally among the top third, middle third and lower third of institutions ranked on the basis of the amount of dollars awarded by PHS for research in FY 1991, i.e., the "research grants base."
- o Availability of funds.

INQUIRIES

Direct inquiries regarding programmatic issues to:

BRS Program Office
Westwood Building, Room 10A11
Bethesda, MD 20892
Telephone: (301) 496-6743

Direct inquiries regarding fiscal matters to:

National Center for Research Resource
Office of Grants and Contracts Management
Westwood Building, Room 853
Bethesda, MD 20892
Telephone: (301) 496-9840

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.337, Biomedical Research Support. Awards will be made under authorization of the Public Health Service Act, Title III, Part A, (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241) and administered under PHS grants policies and Federal Regulations 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

ANTIPHOSPHOLIPID ANTIBODY AND LUPUS ANTICOAGULANT

NIH GUIDE, Volume 21, Number 5, February 7, 1992

PA NUMBER: PA-92-39

P.T. 34; K.W. 0715015, 0710070, 0755020, 0765035

National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Heart, Lung, and Blood Institute

PURPOSE

The Arthritis Research Program of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) supports research on the autoantibodies found in patients with systemic lupus erythematosus. The Thrombosis and Hemostasis Branch of the National Heart, Lung, and Blood Institute (NHLBI) supports research on hypercoagulability and thrombosis. The NIAMS and the NHLBI, through this program announcement, encourage the submission of grant applications for basic and clinical research related to antiphospholipid antibody and the lupus anticoagulant.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Biology of Autoimmune Antiphospholipid Antibody and Lupus Anticoagulant, is related to the priority areas of health promotion: maternal and infant health and heart disease and stroke. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged. Foreign institutions are not eligible for the K awards.

MECHANISM OF SUPPORT

Investigators may apply for research project grants (R01), First Independent Research Support and Transition (FIRST) awards, (R29), and career development (K04, K08, K11) awards.

RESEARCH OBJECTIVES

Background

Autoimmune antiphospholipid antibody and lupus anticoagulant, two closely related antibodies, are associated with a clinical syndrome consisting of recurrent thromboocclusive disease, livedo reticularis, and repeated in utero fetal deaths. Many persons with this antibody do not have systemic lupus erythematosus and some are apparently well. Among persons with clinical illness attributable to antiphospholipid antibody, there is considerable heterogeneity of symptoms and of antibody characteristics. The mechanisms by which clinical events occur are unknown. A serum cofactor, apolipoprotein H, is generally required for the binding of autoimmune antibody to phospholipid in the most commonly used solid phase assay, but precise knowledge concerning the physical nature of the antigen and the relevance of the cofactor in antibody binding is still lacking. Animal models for the antibody and for the syndrome do not currently exist. Although anticoagulation with drugs, such as aspirin or warfarin, are frequently used for treatment, there is as yet no uniform regimen for all clinical conditions associated with the antibodies and no definitive clinical trials have yet been conducted.

On September 25, 1991, the NIAMS and the NHLBI co-sponsored an Antiphospholipid Antibody/Lupus Anticoagulant Workshop. This Workshop identified research issues that form the basis of this program announcement. These

issues include: the nature of the relationship between antiphospholipid antibody and lupus anticoagulant; the roles of apolipoprotein H and of other phospholipid binding proteins in antibody binding and in clinical illness; the chemical or structural nature of the antigen or epitope; the (presumably) exogenous trigger for induction and maintenance of antiphospholipid antibody in patients; the reasons for patient heterogeneity; and the construction of animal models. Treatments for the various clinical manifestations of the syndrome comprise an additional question.

Research Goals and Scope

The primary goal of this program announcement is to foster research that enhances knowledge about mechanisms of action of antiphospholipid antibody. This goal includes, but is not limited to, studies that integrate multidisciplinary approaches.

The scope of possible research areas includes, but is not limited to, the following topics:

- o Studies of phospholipid structure relevant to antigenicity;
- o Studies of the interaction of phospholipid-binding proteins, including annexins and antiphospholipid antibodies, with phospholipids;
- o Studies of the induction and/or maintenance of antiphospholipid antibody;
- o Studies defining the differences and/or similarities between antiphospholipid antibody and lupus anticoagulant;
- o Elucidation of the mechanisms by which lupus anticoagulants and phospholipid antibodies promote hypercoagulability and thromboembolic events;
- o Studies of the pathophysiology of fetal death associated with antiphospholipid antibodies;
- o Animal models;
- o Clinical studies, including differences and/or similarities between patients with systemic lupus erythematosus and those with primary antiphospholipid antibody syndrome;
- o Treatment trials.

Investigators are encouraged to use the full range of current disciplines and techniques available to them.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the

information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may want to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC Program Director or Principal Investigator must be included with the application.

Applications are to be submitted on the grant application form PHS 398 (rev. 10/88) (applications submitted after May 1 are to use the PHS 398 (rev 9/91)) and will be accepted at the standard application deadlines as indicated in the application kit.

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, MD 20892, telephone 301/496-7441. The title and number of the announcement must be typed in Section 2 on the face page of the application.

The completed original application and six legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. R01 and R29 applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH. Initial review of applications for the K series will be by the review group of the relevant Institute or Center in accordance with the standard NIH peer review procedures. Following scientific/technical review, the applications will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that ICD. The following will be considered making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Lawrence Petrucci, Ph.D.
Arthritis Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 406
Bethesda, MD 20892
Telephone: (301) 496-7326

or

Carol H. Letendre, Ph.D.
Acting Chief, Thrombosis and Hemostasis Branch
Division of Blood Diseases and Resources
National Heart, Lung and Blood Institute
Federal Building, Room 516
Bethesda, MD 20892
Telephone: (301) 496-8966

Direct inquiries regarding fiscal matters to:

Diane M. Watson
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 407-A
Bethesda, MD 20892
Telephone: (301) 496-7495

or

Jane R. Davis
Section Chief, Blood Diseases and Resources
National Heart, Lung and Blood Institute
Westwood Building, Room 4A15C
Bethesda, MD 20892
Telephone: (301) 496-7257

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Numbers 93.846, Arthritis, Musculoskeletal and Skin Diseases Research and 93.839, Blood Diseases and Resources Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

POST-POLIO SYNDROME

NIH GUIDE, Volume 21, Number 5, February 7, 1992

PA NUMBER: PA-92-40

P.T. 34; K.W. 0715125, 0785055, 0765035, 0710070, 0755020

National Institute of Neurological Disorders and Stroke

PURPOSE

The National Institute of Neurological Disorders and Stroke (NINDS) encourages the submission of applications for research grants related to the post-polio syndrome. The NINDS invites grant applications to support research in all aspects of the post-polio syndrome including epidemiology, diagnosis, pathophysiology, immunology, therapy, and the development of animal models.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention goals of "Healthy People 2000," a PHS-led national activity for setting priorities. This program announcement, Post-polio Syndrome, is related to the priority area of diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone: 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged.

MECHANISMS OF SUPPORT

Support for this program announcement will be the Research Project Grant (R01), Research Program Project (P01), Research Center Grant (P50), and First Independent Research Support and Transition (FIRST) Award (R29). Prospective applicants are encouraged to communicate with the NINDS staff contact listed under INQUIRIES regarding the appropriate funding mechanism. Both basic science and clinical investigations are encouraged to address relevant research issues.

RESEARCH OBJECTIVES

Background

Survivors of paralytic poliomyelitis have begun to suffer renewed neurological and neuromuscular symptoms decades after maximum recovery from the acute disease. Symptoms include a form of progressive muscular atrophy that involves new muscle weakness affecting certain muscle groups, pain, fatigue, and decreased physical endurance. Individuals who have fully recovered from the initial episode and those who still have residual effects are at risk. A number of terms have been proposed to describe these late effects including post-polio

syndrome, post-polio motor neuron disease, and post-polio muscular atrophy.

Estimates of the number of survivors of paralytic poliomyelitis in the United States vary widely, from about 250,000 to over 1 million. A 1984 epidemiological study performed by the Mayo clinic found that 25 percent of survivors had renewed symptoms, but a later follow-up of a sample of the original respondents showed that 66 percent were experiencing new weakness.

Pathologic mechanisms involved in the post-polio syndrome are not understood, and there is evidence supporting several etiological theories. Changes in the motor neuron have been studied extensively. After recovery from acute polio, axons of surviving motor neurons sprout to reinnervate muscles whose original motor neuron did not survive. It is hypothesized that this process is ongoing for several years, after which the capacity of the motor neuron to reinnervate additional muscles is reached and the nerve terminals begin to degenerate.

A recent report of IgM antibodies to the polio virus in some patients with recurring weakness suggests that late effects of the long dormant polio virus may play a role. Other hypotheses that have been studied include neuromuscular changes caused by premature aging in polio patients, an immunological mechanism, and spinal cord changes affecting motor neurons.

Research Goals and Scope

Multidisciplinary or collaborative studies of the post-polio syndrome are encouraged. Examples are given below, but applications are not limited to these areas of research:

- o Epidemiological studies to determine the prevalence of post-polio syndrome and to develop standardized diagnostic criteria.
- o Pathogenetic studies emphasizing the relative stability of reinnervation following infection with the polio virus, terminal sprouting, and growth factors.
- o Animal models to study the pathogenesis of the original insult, reinnervation, possible reappearance of symptoms, and restoration of function.
- o Use of new molecular biological techniques such as cloned polio cDNAs and the polymerase chain reaction (PCR) to detect the polio virus.
- o Development of strategies of immunotherapy if it is determined that an autoimmune mechanism is involved.
- o Development of therapeutic strategies to improve or restore neuromuscular function.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Section 2, A-D of the research plan AND summarized in Section 2, E, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the

information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed and the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications must be submitted on the grant application form PHS 398 according to instructions contained in the application kit. Applications submitted after May 1, 1992, are to use the 9/91 revision of the form PHS 398. Application kits are available from most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, MD 20892, telephone 301-496-7441.

Check "yes" in item two on the face page of the application and type "Post-Polio Syndrome, PA-92-40."

Applicants for the P01 or P50 must use the application format as described in the NINDS pamphlet, "Application Guidelines: Program Project and Clinical Research Center Grants," that may be obtained from the contacts listed under INQUIRIES.

Deadlines for the receipt of applications are February 1, June 1, and October 1. The completed original application and six legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be judged on scientific merit and program relevance in accordance with NIH policy and procedures involving peer review. An initial review will be made by an appropriate study section of the Division of Research Grants for research grants and FIRST awards and by an appropriate institute committee for program projects and centers. A second level of review will be made by an appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be used in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

For further information regarding this announcement, potential applicants may write or call:

Paul L. Nichols, Ph.D.
Developmental Neurology Branch
Division of Developmental, Convulsive, and Neuromuscular Disorders
National Institute of Neurological Disorders and Stroke
Federal Building, Room 8C08
Bethesda, MD 20892
Telephone: (301) 496-5821

For fiscal and administrative inquiries regarding this announcement, potential applicants may write or call:

Dwight H. Mowery, Jr.
Grants Management Specialist
Grants Management Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 1004
Bethesda, MD 20892
Telephone: (301) 496-9231

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.853 Clinical Research Related

Neurological Disorders and 93.854 Biological Basis Research in the Neurosciences. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-150, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ERRATUM

NIH LIBRARY



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MINORITY SCHOOL FACULTY DEVELOPMENT AWARD

NIH GUIDE, Volume 21, Number 5, February 7, 1992

PA NUMBER: PA-92-32

P.T. 14, FF; K.W. 0715035, 0710030

National Cancer Institute

Application Receipt Dates: February 1, 1992, June 1, 1992, October 1, 1992

This program announcement, Minority School Faculty Development Award, was published in the NIH Guide for Grants and Contracts on January 17, 1992, Vol. 21, No. 2. This erratum corrects the information in the MECHANISM OF SUPPORT section. The correct funding mechanism for this program is the Minority School Faculty Development Award (K14).

INQUIRIES

Direct inquiries concerning this program to:

Dr. Lemuel Evans
Division of Extramural Activities
Comprehensive Minority Biomedical Program
National Cancer Institute
Building 31, Room 10A04
Bethesda, MD 20892
Telephone: (301) 496-7344
FAX: (301) 402-0062

EXPLORATORY CENTERS FOR BIOBEHAVIOR SYMPTOM MANAGEMENT

NIH GUIDE, Volume 21, Number 5, February 7, 1992

RFA: NR-92-02

P.T. 04; K.W. 0715020, 0785130, 0404000, 0785035, 0710030

National Center for Nursing Research

Letter of Intent Receipt Date: March 31, 1992

Application Receipt Date: May 7, 1992

The notice of availability for this Request for Applications was published in the NIH Guide for Grants and Contracts on January 24, 1992, Vol. 21, No. 3, Part II of II. The section, RESEARCH OBJECTIVES, contained an error in the third paragraph. This entire paragraph, shown below, indicates that "symptoms specific to psychiatric disorders are not included in the scope of this RFA."

The theoretical basis for the planned feasibility/pilot studies must be clearly explicated for the behavioral, psychosocial, and physiological strategies described in the exploratory center grant application. The symptom(s) for exploration is to be selected by the applicants and may include, but is not limited to, the high priority symptoms of pain, fatigue, dyspnea, nausea, vomiting, cognitive impairment, altered sleep or rest patterns, and depression or anxiety secondary to a physical illness. However, symptoms specific to psychiatric disorders are not included in the scope of this RFA. One or more symptoms may be selected by each applicants depending on the scientific expertise available at the applicant institution or clinical setting and the theoretical basis chosen to explicate the research. An interdisciplinary approach must be utilized. Although feasibility/pilot studies addressing only pharmacological interventions are not acceptable, the inclusion of pharmacological strategies in combination with non pharmacologic strategies is appropriate for a multimodal management approach.

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For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21, No. 6
February 14, 1992

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* 340189
-51350E**

929 WILD FOREST DRIVE
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NOTICES OF AVAILABILITY (RFPs AND RFAs)

PERIPHERAL ARTERIAL DISEASE: A PILOT STUDY TO EVALUATE TREATMENT AND PREVENTION STRATEGIES FOR ATHEROSCLEROTIC CARDIOVASCULAR DISEASE--CLINICAL CENTERS

NIH GUIDE, Volume 21, Number 6, February 14, 1992

RFP AVAILABLE: NHLBI-HC-92-11

P.T. 34; K.W. 0715040, 0760002

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) requires six clinical centers to participate in a pilot study to evaluate the exact dosage of various drugs and drug combinations, drug interactions, and adverse effects by monitoring a variety of biochemical markers of atherosclerotic cardiovascular disease. This pilot study will also assess the feasibility of conducting a full-scale trial among patients with peripheral arterial disease (PAD). The pilot study will employ a factorial design in 600 participants with documented PAD (symptomatic and asymptomatic). The three interventions will consist of: (1) isolated increase in plasma HDL-C levels, (2) antithrombotic therapies of warfarin and aspirin, and (3) antioxidant therapy. The period of performance is anticipated for three years beginning in September 1992.

This is an announcement of the availability of a Request for Proposals (RFP). RFP NHLBI-HC-92-11 will be available on or about February 11, 1992, with proposals due on April 24, 1992. Six awards are anticipated by the Government. Offerors other than those in the North American continent will not be considered. Written requests for this RFP must include three, self-addressed mailing labels and must cite RFP NHLBI-HC-92-11.

Requests for copies of the RFP must be sent to:

Linda Y. Gardner
Contract Specialist
ECA Contracts Section
National Heart, Lung, and Blood Institute
Federal Building, Room 200
7550 Wisconsin Avenue
Bethesda, MD 20892

PHYSIOLOGY AND PATHOPHYSIOLOGY OF THE PANCREATIC DUCTS

NIH GUIDE, Volume 21, Number 6, February 14, 1992

RFA AVAILABLE: DK-92-16

P.T. 34; K.W. 1002061, 0765035, 0715085

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: June 15, 1992

Application Receipt Date: July 15, 1992

NOTE THAT THE FULL TEXT OF THIS RFA SHOULD BE REQUESTED: SEE INQUIRIES SECTION

PURPOSE

The Division of Digestive Diseases and Nutrition, and the Division of Diabetes, Endocrinology and Metabolism of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) announces the availability of a request for applications (RFA) that conduct basic and clinical studies into the physiology and pathophysiology of the pancreatic ducts.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Basic and Clinical Studies on the Physiology and Pathophysiology of the Pancreatic Ducts, is related to the priority area of diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Minority individuals and women are encouraged to apply.

MECHANISM OF SUPPORT

Support of this program will be through the NIH grant-in-aid research project grant (R01) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Except as otherwise stated in this announcement, awards will be administered under PHS grants policy as stated in the PHS Grants Policy Statement.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and will be reviewed according to the customary NIH peer review procedures. The total requested project period for applications submitted in response to this RFA may not exceed five years. A maximum of three years may be requested for foreign awards. The earliest possible award date will be April 1, 1993.

FUNDS AVAILABLE

For FY 93, \$1.0 million will be committed to fund applications submitted in response to this RFA. It is anticipated that five to seven awards will be made. However, this funding level is dependent upon the receipt of a sufficient number of applications of high scientific merit. In order to help meet NIDDK goals for managing the costs of biomedical research, applicants may not request more than \$160,000 direct costs for the initial budget period. Although this program is provided for in the financial plans of the NIDDK, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

A neglected but very important component of the pancreas, the pancreatic ductules and duct system, was the subject of a three-day conference held in September 1991. Because duct cells represent only about 10 percent of the adult exocrine pancreas, they have been difficult to study. Recently, investigators have been able to use tissue culture and microdissection techniques to study duct cells in vitro. The ion transport, neural and hormonal regulation, and other electrophysiological measurements of these cells can now be made in health and disease. Some of the common diseases of pancreatic ducts are pancreatitis, cystic fibrosis, and adenocarcinoma. All of these basic and clinical areas offer opportunities to expand our knowledge of the physiology and pathophysiology of the pancreatic duct system.

STUDY POPULATIONS

It is NIH policy that women and minorities must be included in clinical study populations unless there is a good reason to exclude them. The study design must seek to identify any pertinent gender or minority population differences.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 15, 1992, a letter of intent that includes a descriptive

title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIDDK staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Chief, Review Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
5333 Westbard Avenue, Room 605
Bethesda, MD 20892
Telephone: (301) 496-7083

APPLICATION PROCEDURES

The research grant application form PHS 398 (revised 9/91) is to be used in applying for these grants. The form is available from most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/496-7441.

REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated by an appropriate peer review group convened by the NIDDK in accordance with the usual NIH peer review procedures. Following review, the applications will be given a secondary review by the NIDDK Advisory Council unless not recommended for further consideration by the initial review group. Applications that are incomplete or unresponsive to the RFA will be returned to the applicant or held until the next regular receipt date and reviewed by the Division of Research Grants if so requested by the applicant.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The RFA may be obtained from:

Sarah C. Kalser, Ph.D.
Pancreatic Diseases Program Director
Division of Digestive Diseases & Nutrition
National Institute of Diabetes and Digestive and Kidney Diseases
5333 Westbard Avenue, Room 3A-17
Bethesda, MD 20892
Telephone: (301) 496-7858

Inquiries regarding fiscal matters should be directed to:

Ms. Thelma Jones
Grants Management Specialist
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
5333 Westbard Avenue, Room 649
Bethesda, MD 20892
Telephone: (301) 496-7467

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.847 and No. 93.848. Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

DEVELOPMENT GRANTS: MINORITY ORAL HEALTH RESEARCH CENTERS

NIH GUIDE, Volume 21, Number 6, February 14, 1992

RFA AVAILABLE: DE-92-01

P.T. 04, FF; K.W. 0715148, 0710030

National Institute of Dental Research
National Center for Research Resources

Letter of Intent Receipt Date: March 1, 1992
Application Receipt Date: May 6, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE COMPLETE RFA FROM THE CONTACT LISTED, BELOW.

PURPOSE

The National Institute of Dental Research (NIDR) and the Research Centers in Minority Institutions (RCMI) Program of the National Center for Research Resources (NCRR) invite applications for grants for development of Regional Research Centers for Minority Oral Health (RRCMOH). The purpose of these Phase I grants is to enable minority dental schools or dental schools serving large minority populations to develop the necessary alliances and organizational structure necessary to compete for Phase II grants for the support of RRCMOHs. An RFA for Phase II, five-year grants for support of RRCMOHs will be available in 1994. The objectives of the RRCMOH initiative are to: (1) conduct research to improve the oral health of U.S. racial and ethnic minorities; (2) enhance the research capabilities and participation of members of racial and ethnic minorities in oral health research; and (3) develop and strengthen the minority oral health research infrastructure of minority dental schools and of majority dental schools serving large minority populations. African Americans (Blacks), Hispanics, Asians and Pacific Islanders, and American Indians and Alaskan Natives are considered to be racial or ethnic minorities.

An orientation meeting for potential applicants will be conducted by NIDR and NCRR/RCMI extramural program staff in connection with the annual meeting of the American Association for Dental Research, March 11, 1992, in Boston, Massachusetts. Details of the time and location of the meeting are available from the NIDR staff. A summary of the meeting will be available from the NIDR staff.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Developmental Grants for Regional Research Centers for Minority Oral Health, is related to the priority area of reducing health disparities among Americans by improving oral health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Two types of United States institutions are eligible to apply: minority dental schools or other dental schools serving large populations of minorities. Only the following organizational structures are acceptable:

1. A minority dental school must propose an alliance with one or more research-intensive dental schools. Such a structure may include alliances with one or more other minority institutions.
2. A dental school serving a large minority population must propose an alliance with one or more research-intensive institutions. Such a structure may include alliances with one or more minority institutions. When a dental school serving a large minority population qualifies as a research-intensive institution, alliances must be proposed with one or more minority institutions.

A dental school serving a large minority population is defined as one in which the patient population served is more than 50 percent individuals of the minority racial and ethnic groups listed above. A research-intensive institution is defined as one that received more than \$1 million in dental research and research training support during Fiscal Year 1991. A list of organizations receiving \$1,000,000 or more from the NIDR is provided as an appendix to this RFA. Additional institutions may apply. A minority institution is defined as any educational, health-care, or research institution largely staffed by or serving racial/ethnic minorities.

To be responsive to this RFA, an application must propose collaborative alliances with other institutions, that conform to the organizational structures listed above and address the objectives of the RRCMOH initiative. A research-intensive institution may not be the applicant organization unless it serves a large minority population. Applications proposing alliances between minority institutions without involvement of research-intensive institutions are not acceptable. Regional proximity of the allied institutions would be an asset but, for a variety of reasons, such an arrangement may not be possible.

MECHANISM OF SUPPORT

Awards will be the National Institutes of Health developmental grants (P20). Awards will be for three years and the earliest funding date is September 1, 1992. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant institution; however periodic consultation with NIDR and NCRR/RCMI staff will be expected. This RFA is a one time solicitation by the NIDR and the NCRR/RCMI. A separate RFA soliciting applications for Phase II, five-year, P50 awards to support RRCMOH will be available in 1994. The receipt of a Phase I grant will not be a prerequisite for submission of an application for a Phase II grant.

FUNDS AVAILABLE

It is anticipated that six, three-year awards may be made. No award will exceed \$225,000 in direct costs for the first year. Additional support, up to \$50,000 in direct costs for the first year, may be provided to minority dental schools or other qualified minority institutions for RRCMOH-related faculty development activities.

STUDY POPULATION

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women and minorities are not included in the study populations for clinical studies, a special justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 1, 1992, a letter of intent that includes a descriptive title of the proposed center, the name, address and telephone number of the center director, co-director, the identities of other key personnel and participating institutions, and the number and title of this RFA. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIDR staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

APPLICATION PROCEDURES

Applications must be received by May 6, 1992. Prospective applicants are advised to communicate with program and grants management staff of the NIDR Extramural Program as early as possible in the planning phase of application preparation. The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892; and from the program administrator named below.

REVIEW CONSIDERATIONS

Applications that are complete and responsive will be evaluated for scientific and technical merit by a special review committee convened by the NIDR Scientific Review Office. Applications may be subjected to triage to determine merit relative to other applications. The NIDR will withdraw from further competition those applications judged by triage to be noncompetitive for award and notify the applicant and institutional official. Applications judged to be competitive will undergo further scientific merit review by a special review committee convened by the NIDR. The second level of review will be provided by the National Advisory Dental Research Council.

AWARD CRITERIA

The NIDR appreciates the value of complementary funding from other public and private sources, including foundations and industrial concerns, for activities that will complement and expand those supported by the NIDR and NCRR/RCMI. Such circumstances will be considered in making any award.

INQUIRIES

Requests for the RFA and inquiries related to the RFA may be addressed to:

Matthew Kinnard, Ph.D.
Director, Oral Soft Tissue Diseases and AIDS Program
Extramural Program
National Institute of Dental Research
Westwood Building, Room 509
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7784

Direct inquiries concerning fiscal matters to:

Theresa Ringer
Grants Management Officer
Extramural Program
National Institute of Dental Research
Westwood Building, Room 518
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7437

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.121. Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

THROMBOCYTOPENIAS IN WOMEN AND NEONATES

NIH GUIDE, Volume 21, Number 6, February 14, 1992

RFA AVAILABLE: HL-92-06-B

P.T. 34, AA, II; K.W. 0715040, 0710070, 1002004, 1002008, 0785070

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: March 20, 1992

Application Receipt Date: May 7, 1992

THE REQUEST FOR APPLICATION (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES BELOW.

PURPOSE

The National Heart, Lung, and Blood Institute announces the availability of an RFA on the above subject. The purpose of this initiative is to encourage research that better defines the properties and clinical relevance of the antibodies to platelets in alloimmune and autoimmune thrombocytopenias in women and neonates. It is hoped that the information generated will lead to improved therapy for the patient population.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Thrombocytopenias in Women and Neonates, is related to the priority area of maternal and infant health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-782-3238).

ELIGIBILITY REQUIREMENTS

All domestic public and private, for-profit and non-profit institutions or organizations are eligible to apply in response to this RFA. Awards in connection with this announcement will be made to foreign institutions only for research of very unusual merit, need, and promise, and in accordance with Public Health Service policy governing such awards. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research grant (R01) and is a one-time solicitation. Applicants will plan and execute the research programs and are requested to furnish estimates of the time required to achieve the objectives of the proposed research project. Up to FIVE YEARS of support may be requested. At the end of the award period, renewal applications may be submitted for peer review and competition for support through the unsolicited grant program of the NIH. It is anticipated that support for the present program will begin in September 1992. Administrative adjustments in project period and/or amount of support may be required at the time of the award. All current policies and requirements that govern the research grant programs of the NIH will apply to grants awarded in connection with this RFA.

FUNDS AVAILABLE

Although the financial plans for fiscal year 1992 include \$1.5 million for this program, award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that about six grants will be awarded. The specific amount to be funded will, however, depend on the merit and scope of the applications received and on the availability of funds. Since a variety of approaches would represent valid responses to this announcement, it is anticipated that there will be a range of costs among individual grants awarded. If collaborative arrangements involve sub-contracts with other institutions, the NHLBI Grants Operations Branch (telephone: 301-496-7257) must be consulted regarding procedures to be followed.

RESEARCH OBJECTIVES

The following are examples of research areas, but prospective applicants are urged to use their own ideas regarding the area of research to be explored.

o characterize the etiology and improve the diagnosis of autoimmune thrombocytopenia in women, especially during pregnancy; develop improved methods for differentiating autoimmune thrombocytopenia from "incidental" thrombocytopenia in pregnant women and for assessing the risk that an infant will be born thrombocytopenic and suffer hemorrhagic complications.

o prevalence and pathogenesis of neonatal alloimmune thrombocytopenic purpura and develop improved methods for diagnosis and treatment and for assessment of the risk of neonatal thrombocytopenia and hemorrhagic complications.

o better define the biochemical nature and clinical relevance of the antigens and antiplatelet antibodies involved in immune thrombocytopenia including immunoglobulin subclasses, cytotoxic mechanisms, target antigens,

epitope specificity, antigen frequency amongst minority populations, and cross reactivity with endothelial and other cells.

o improved understanding of platelet production and clearance in women and infants with thrombocytopenia and developmental aspects of allo- and auto-antigen expression on fetal platelets and on megakaryocytic precursors.

o prevalence, pathogenesis and treatment of other forms of thrombocytopenia associated with pregnancy.

The NHLBI will sponsor annual meetings to encourage the exchange of information among investigators who participate in this program.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

The NHLBI requests that prospective applicants submit a letter of intent that includes a descriptive title of the proposed research and identification of other participating institutions. Such letters are requested only for the purpose of providing an indication of the number and scope of applications to be received; therefore, their receipt is not acknowledged. A letter of intent is not binding, will not enter into the review of any application subsequently submitted, nor is it a necessary requirement for applications. This letter of intent, is to be received by March 20, 1992, and is to be sent to:

Dr. Charles L. Turbyfill
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 553
Bethesda, MD 20892
Telephone: (301) 496-7351

APPLICATION PROCEDURES

Applications are to be submitted on the research project grant application form PHS 398 (rev. 9/91). This form is available in an applicant institution's office of sponsored research or business office and the Office of Grants Inquiries, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/496-7441.

In the preparation of the budget for the grant application, applicants should REQUEST ADDITIONAL TRAVEL FUNDS for one meeting each year that will be held in Bethesda, Maryland. Applicants should also include a statement in the applications indicating their willingness to participate in such meetings.

Application Receipt Date: May 7, 1992

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for responsiveness to the objectives of the RFA. If an application is judged unresponsive, the applicant will be contacted to withdraw the application or resubmit as an unsolicited grant application for the next review cycle.

Applications judged to be responsive will be reviewed for scientific and technical merit by an initial review group, that will be convened by the Division of Extramural Affairs, NHLBI, solely to review these applications.

This initial review will include a preliminary evaluation to determine scientific merit relative to the other applications received in response to the RFA (triage). The NHLBI will withdraw from further consideration applications judged to be noncompetitive and promptly notify the Principal Investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated for scientific/technical merit by the usual peer review procedures.

The second level review will be by the National Heart, Lung, and Blood Advisory Council.

INQUIRIES

Inquiries regarding this program and requests for the RFA document are to be addressed to:

Dr. Pankaj Ganguly
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building, Room 5C14
Bethesda, MD 20892
Telephone: (301) 402-2237

For fiscal and administrative matters, contact:

Ms. Jane R. Davis
Chief, Blood Division Grants Management Section
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A11
Bethesda, MD 20892
Telephone: (301) 496-7257
FAX: (301) 402-1200

AUTHORITY AND REGULATIONS

The programs of the Division of Blood Diseases and Resources, NHLBI, are described in the Catalog of Federal Domestic Assistance Number 93.839. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grants policies and Federal regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

CLINICAL INVESTIGATOR AWARD FOR RESEARCH ON SPECIAL POPULATIONS

NIH GUIDE, Volume 21, Number 6, February 14, 1992

PA NUMBER: PA-92-41

P.T. 34; K.W. 0715035, 0745020, 0745027, 0745070

National Cancer Institute

Application Receipt Dates: June 1, 1992, October 1, 1992, February 1, 1993

PURPOSE

The Comprehensive Minority Biomedical Research Program, Division of Extramural Activities, National Cancer Institute (NCI), announces the availability of Clinical Investigator Awards for Research on Special Populations. The term "special populations" refers to those population segments that may experience or are known to experience high cancer rates and are underserved in terms of: cancer prevention and control programs (e.g., smoking cessation and health screening programs); diagnostic and treatment modalities; study for special risk factors or underlying biological differences; and access to routine medical care. The definition of special populations includes: African Americans, Alaska Natives, American Indians, Asian Americans, Pacific Islanders, Hispanics, the elderly, and low-income groups.

The award will enable candidates to undertake three to five years of special study and supervised research experience tailored to individual needs with a sponsor (or sponsors) who is competent to provide research guidance. This award is intended to cover the transition between postdoctoral research experience and an independent research career and to acquaint the candidate with the often unique challenges and circumstances involved in designing research protocols directed toward improving the health of groups comprising a significant and often disproportional percentage of individuals at risk from high cancer morbidity and mortality rates. It is anticipated that the experience and results achieved by the awardee from this special grants program, in the majority of cases, will provide the basis for successful competition in the independent research support programs of the NCI.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement (PA), Clinical Investigator Award for Research on Special Populations, is related to the priority area of cancer research. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

The award is designed to provide intensive, supervised research experience on the above designated topics. Although the award is primarily for individuals with an M.D. degree, applications will be accepted from M.D.s and D.O.s who have a Ph.D. or an equivalent research degree if special circumstances can be shown such as a Ph.D. in an unrelated field or an intervening period of clinical training since the completion of the Ph.D. These applications will be considered on a case-by-case basis.

If the candidate has less than three or more than seven years of postdoctoral experience at the time of application, a strong justification for an exception must be included in the application and must be clearly indicated as such.

Candidates must have completed their clinical training by the time of award, have documented competence in

clinical activities, and have research experience in the chosen area of interest. Candidates must provide evidence of a serious intent for research and academic careers and an interest in medical issues associated with special populations.

Candidates from minority and non-minority institutions may apply.

Applicants for this Clinical Investigator Award may not submit a concurrent application for an NIH Research Career Development Award (K11), Academic Award (K07), First Independent Research Support and Transition (FIRST) Award (R29), or a research project grant (R01). However, an Awardee of this program may apply subsequently for a research project grant or a FIRST Award.

The grantee institution must be a domestic nonprofit research institution, school, or comparable institution with strong, well-established research and training programs, adequate numbers of highly trained faculty in clinical and basic science departments, and development of independent research careers.

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health Clinical Investigator Award (K08). Applicants will be responsible for the planning, direction, and execution of the proposed project. Except as otherwise stated in this PA, awards will be administered under PHS Grants Policy Statement, DHHS Publication No. (OASH) 90-50,000, revised October 1, 1990.

Conditions of the Award

Applicants may request three to five years of support. Awards are non-renewable and non-transferable from one awardee institution to another. Funding beyond the first year of the grant is contingent on satisfactory progress during the preceding year.

Allowable costs may include:

- o Awardee's Salary: a maximum of \$50,000 per year for full-time support; in addition, fringe benefits will be provided. Institutional supplementation is permitted.
- o Research Support: a maximum of \$10,000 annually for years 01 and 02 and \$20,000 annually for succeeding years to provide the categories listed below.
- o Equipment: specialized research equipment essential to the proposed program. The available facilities should include most of the necessary equipment.
- o Supplies: consumable supplies essential to the proposed program.
- o Travel: domestic travel essential to the proposed program.
- o Tuition for Training Courses: if essential to the awardee's individual research development program.
- o Other: publication costs, patient costs, and other expenses necessary for the research program.

Indirect Costs - The indirect cost rate may not exceed eight percent of the total allowable direct costs. The grantee institution's share of the fringe benefits may be paid as a direct cost (if not treated as an indirect cost) on that portion of the salary provided by the Clinical Investigator Award.

RESEARCH OBJECTIVES

- o To increase the number of physician-investigators in medical oncology, surgical oncology, preventive oncology, and diagnostic and therapeutic radiology and epidemiology, nutrition, and behavioral medicine, as they relate to cancer, who are committed to investigate the unique problems facing special populations.
- o To provide an opportunity for clinically trained physicians with a commitment to research to develop as independent biomedical research investigators.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or in adequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study populations must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS

398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying to this program. These forms are available at most institutional business offices, from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892, and from the NCI program director named below.

Submit a signed, typewritten original of the application, including the Checklist, and four signed, exact photocopies, in one package to the address below. The photocopies must be clear and single sided.

DIVISION OF RESEARCH GRANTS
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892

At time of submission, send two additional copies of the application to:

REFERRAL OFFICER
Division of Extramural Activities
National Cancer Institute
Westwood Building, Room 848
5333 Westbard Avenue
Bethesda, MD 20892

The receipt dates for all applications are found in the form PHS 398 instructions. The title and number of this announcement must be typed on line 2 of the application face page and the box must be checked YES.

Candidates must provide a description of the proposed research and career development plan for the period of the award in Section 2 of the application under the heading "Research Plan." The candidate must be prepared to commit full-time effort to the objectives of this award. It is required that a minimum of 75 percent effort be devoted to the research program. The remaining 25 percent may be divided among other activities such as teaching and clinical training pursuits only if they are consonant with the program goals, i.e., the awardee's development into an independent biomedical research investigator.

The reasons for a commitment to research in the problems facing special populations with respect to cancer must be indicated.

The sponsor must provide:

- o His/her concept of a development and research plan for the awardee.
- o A current curriculum vitae with a complete bibliography and research support.
- o A letter indicating his/her evaluation of the proposed awardee and his/her willingness to provide guidance and support.

Evidence of the commitment of the institution to the candidate's research and development must be provided.

Adequate access to populations comprised of one or more of the groups targeted by this award must be demonstrated.

REVIEW PROCEDURES

Upon receipt, applications will be reviewed initially by the Division of Research Grants (DRG) for completeness and will be assigned on the basis of Public Health Service referral guidelines. Incomplete applications will be returned to the applicant without further consideration.

Applications will be reviewed for scientific and technical merit by an appropriate peer review group convened by the relevant Institute or Center. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council. Criteria for the initial review include:

- o The candidate's potential for a career in independent research.
- o The candidate's commitment to a research career.
- o The overall merit of the candidate's plan for research and the development of research skills.
- o The quality of the candidate's clinical training and experience.
- o The institution's ability to provide quality facilities, resources, and opportunities necessary to the candidate's research development.
- o Presence of highly trained faculty in clinical and basic science departments relative to the area of study.
- o The ability and plans of the sponsor (or sponsors) who will provide the candidate with the guidance necessary for career development in research.

The review group will recommend an appropriate budget for each approved application.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement



INQUIRIES

Written and telephone inquiries to clarify any issues or questions from potential applicants are encouraged and may be directed to:

Dr. Lemuel A. Evans
Division of Extramural Activities
Comprehensive Minority Biomedical Program
National Cancer Institute
Building 31, Room 10A04
Bethesda, MD 20892
Telephone: (301) 496-7344
FAX: (301) 402-0062

For information regarding budgetary/administrative issues related to this PA, contact:

Ms. Carolyn Mason
Grants Management Specialist
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800, Extension 59

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.398, Cancer Research Manpower. Awards are made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Happy Valentines Day



NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21, No. 7, Part 1 of 2
February 21, 1992

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NOTICES

PUBLIC HEARING ON WOMEN IN BIOMEDICAL CAREERS

NIH GUIDE, Volume 21, Number 7, February 21, 1992

P.T. 42, II; K.W. 1014002

National Institutes of Health

The Office of Research on Women's Health (ORWH), Office of the Director, National Institutes of Health, will hold a public hearing on March 2 and 3, 1992, from 8:00 a.m. to 4:30 p.m., in Wilson Hall, Building 1, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland. The purpose of this hearing is to accept public testimony from individuals and organizations interested in the subject of recruitment, retention, re-entry, and advancement of women in biomedical careers.

This testimony will be used to help the members of the ORWH Planning Task Force on Women in Biomedical Careers (the Task Force) to frame the issues and develop the agenda for an ORWH-sponsored workshop to formulate recommendations to increase the recruitment, retention, re-entry, and advancement of women in biomedical careers to be held on June 11 and 12, 1992, in Bethesda, Maryland. Task Force members will be present at the public hearing to accept testimony.

The number of women admitted to health professional schools and into doctoral and post-doctoral programs is increasing. Yet, the numbers of women in leadership positions in biomedical careers (such as tenured professors, departmental chairs, deans, senior scientists, and principal investigators) are not commensurate. Barriers to entry and advancement continue to exist. Training grants and fellowships often do not take into account a woman scientist's family responsibilities and assumption of non-traditional roles, which often occur at crucial times in her scientific career. Minority women, in particular, often are not presented with opportunities to prepare themselves for scientific and/or academic careers during critical stages in their education. The "glass ceiling" effect, a situation in which women are promoted to within close proximity of major leadership positions but infrequently attain these positions, continues unabated. New ways to retain and advance women in these careers must be identified and implemented.

All sessions are open to the public. However, seating is limited and will be on a first-come, first-served basis. Testimony for the public hearing should be confined to comments relating to recruitment, retention, re-entry, and advancement of women in biomedical careers. Due to time constraints, only one representative from each organization will be allowed to present oral testimony. Each presentation must be limited to five to seven minutes.

A letter of intent to present such testimony should be sent by interested individuals and organizations to the attention of Ms. Margaret Pickerel of Prospect Associates (see address below). The letter of intent to present testimony and three written copies of the testimony, including a brief description of the organization, must be received by Prospect Associates no later than 5:00 p.m. (EST) on February 26, 1992. The date and time at which the letter of intent is received at Prospect Associates will establish the order of presentation at the March hearing.

Written testimony received after that date and time will be accepted, but may not be included in the materials

available to the Task Force members at the March 2 and 3, 1992 hearing.

Organizations wishing to provide only written statements may send three copies of their statements to the address below by February 26, 1992, no later than 5:00 p.m. (EST). All written testimony received by that date will be made available to Task Force members prior to the March meeting. Testimony received after that date will be sent to Task Force members, but may not be available at the March meeting.

INQUIRIES

Ms. Margaret Pickerel
Prospect Associates
1801 Rockville Pike, Suite 500
Rockville, MD 20852
Telephone: (301) 468-6555
FAX: (301) 770-5164

NOTICES OF AVAILABILITY (RFPS AND RFAs)

INTERVENTIONS TO MANAGE ALZHEIMER'S DISEASE SYMPTOMS

NIH GUIDE, Volume 21, Number 7, February 21, 1992

RFA AVAILABLE: NR/AG-92-03

P.T. 34; K.W. 0715180, 0715020, 0414015

National Center for Nursing Research
National Institute on Aging

Letter of Intent Receipt Date: May 1, 1992
Application Receipt Date: June 10, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACTS NAMED IN INQUIRIES BELOW.

PURPOSE

The National Center for Nursing Research (NCNR) and the National Institute on Aging (NIA) invite research grant applications for preliminary investigations that will lead to large-scale clinical studies on the assessment and nonpharmacological management of secondary symptoms exhibited by patients with Alzheimer's disease and related disorders (AD).

HEALTH PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Interventions to Manage Alzheimer's Disease Symptoms, is related to the priority areas of older persons as a targeted group and to chronically disabling conditions. Potential applicants may obtain a copy of the "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed three years. This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures. The anticipated award date will be September 30, 1992.

FUNDS AVAILABLE

Approximately \$1,300,000 in total costs for the first year will be committed to fund applications submitted in response to this RFA. It is anticipated that 13 applications will be funded. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Up to \$75,000 direct costs will be allocated for each award in each funding year, not to exceed three years. Although this program is provided for in the financial plans of the NCNR and the NIA, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

Estimates indicate that 4 million Americans presently suffer from AD. The impact of AD on patients, families, and society is severe and is anticipated to grow as older persons, the group most at risk for AD, continue to increase in number. Although it may not yet be possible to prevent, treat, or permanently alter the course of the underlying disease, interventions can be developed and systematically tested that reduce the patient's secondary symptoms and preserve function. In addition to cognitive symptoms, non-cognitive secondary symptoms are frequently seen across the course of Alzheimer's disease and present significant management problems. These symptoms of special concern may include, but are not limited to, wandering, disturbed sleep, pacing, agitation, feeding and dressing difficulties, incontinence and toileting difficulties, screaming and other vocalizations, aggression and violence, and inappropriate sexual behavior. These symptoms not only contribute to decisions to institutionalize affected individuals, but also lead to the use of chemical and physical restraints.

While there exists a great deal of clinical and anecdotal information about methods that can effectively deal with individual symptoms, little data exist that have been obtained with the rigor of design and procedures of the controlled clinical trial. Therefore, applications are solicited for preliminary investigations and feasibility studies of protocols that will lay the groundwork for the development of rigorous controlled clinical trials to test interventions for the management of the secondary symptoms.

These preliminary studies may address any of the scientific assessment, design, methodological, and intervention problems to facilitate the launch of large-scale clinical trials. For example, satisfactory assessment techniques and instruments for addressing the previously noted problematic symptoms are needed. Studies are needed of strategies for enhancing AD patients' self-care abilities. Delineation of appropriate interventions for an individual symptom or cluster of symptoms and methods for implementing the interventions must be identified. In particular, attention is needed to the affected person's past daily practices and preferences in order to adjust care to such characteristics. Although the primary focus is on nonpharmacologic interventions, research is also needed that addresses the multimodal treatment approaches including, but not limited to, pharmacological interventions for managing symptoms. Studies addressing only pharmacological interventions are not acceptable.

Information on the acceptability, safety, and rationale for the effectiveness of interventions must be obtained prior to undertaking any large-scale trial. Carefully developed interventions for testing in controlled clinical trials at long-term care institutions are needed. Procedures for maintaining interventions across the duration of the trial, using existing nursing home staff, are not clear. Therefore, behavioral, environmental, social, and organizational interventions, individually or in combination, may be proposed and examined. The research may address patient issues in either institutional or noninstitutional settings. Either formal or informal caregivers may be included in the research, but outcome measures must include one or more patient variables. Studies that address the interrelatedness of the biological, behavioral, and cognitive factors of patients are encouraged.

Applications are invited to support projects that address issues including, but not limited to:

- o the identification of underlying factors in research subjects that result in behavioral symptoms and interventions to address these factors.
- o the design and testing of interventions that will lead to the nonpharmacologic management and treatment of the secondary symptoms exhibited by patients with AD.
- o provision of a rigorous scientific base that will lead to controlled clinical trials in institutional or noninstitutional settings by delineating approaches for the management of symptoms, the duration of change, and the procedures required to maintain the change, if possible.

SPECIAL INSTRUCTIONS TO REGARDING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit by May 1, 1992, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows the NCNR and NIA staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Ethel B. Jackson, D.D.S.
Chief, Office of Scientific Review
National Center for Nursing Research
Building 31, Room 5B19
Bethesda, MD 20892
Telephone: (301) 496-0472
FAX: (301) 480-4969

APPLICATION PROCEDURES

The RFA contains important information for applicants and may be obtained from the contacts listed in the INQUIRY section. The application receipt date is June 10, 1992. The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892 telephone 301/496-7441. Applications must be submitted to the NIH Division of Research Grants and will be assigned to a special review group organized by NCNR and NIA. Following this review, applications will be considered by the national advisory councils.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NCNR or NIA staff will contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next review cycle.

Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by NCNR and NIA. The second level of review will be provided by the NCNR and NIA advisory councils.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged and are to be directed to either of the following individuals. The program staff welcome the opportunity to clarify any issues or questions from potential applicants.

Direct inquiries regarding programmatic issues to either:

Mary D. Lucas, Ph.D., R.N.
Chief, Acute and Chronic Illness Branch
National Center for Nursing Research
Westwood Building, Room 754
Bethesda, MD 20892
Telephone: (301) 496-0523

Teresa S. Radebaugh, Sc.D.
Chief, Dementias of Aging
Neuroscience and Neuropsychology of Aging
National Institute on Aging
Gateway Building, Room 3C307
7201 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-9350

Direct inquiries regarding fiscal matters to:

Sally A. Nichols
Grants Management Officer
National Center for Nursing Research
Building 31, Room 5B06
Bethesda, MD 20892
Telephone: (301) 496-0237

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.336, Nursing Research, and No. 93.866. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MENTAL HEALTH CLINICAL TRAINING GRANTS: INDIVIDUAL FACULTY SCHOLAR AWARDS

NIH GUIDE, Volume 21, Number 7, February 21, 1992

RFA AVAILABLE: MH-92-06

P.T. 44; K.W. 0715095, 0715177, 0715072, 0710105

National Institute of Mental Health

Application Receipt Date: April 24, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES BELOW.

PURPOSE

There is a marked disparity between the need for treatment of persons with major mental disorders and the availability of appropriately trained mental health professionals to assess, provide, and supervise the treatment. For this reason, the National Institute of Mental Health (NIMH) supports the Individual Faculty Scholar Awards program to develop a cadre of academically based faculty scholars who will guide the training of professionals in the core mental health disciplines (psychiatry, social work, psychology, psychiatric nursing, and marriage and family therapy) and who will play major leadership roles in the continued development of their professions.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000". PHS urges applicants to submit work plans that address specific objectives of "Healthy People 2000." Potential applicants may obtain a copy (Full Report: Stock Number 017-001-00474-0 or Summary Report: Stock Number 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone: 202-783-3238).

ELIGIBILITY REQUIREMENTS

On behalf of a qualified nominee, applications may be submitted by an academic department or professional school in a U.S. college, university, or nonprofit mental health training institution.

Nominees must be U.S. citizens or have been lawfully admitted to the United States for permanent residence. Nominees must have a full-time academic appointment or be assured of such an appointment upon completion of this award. Women and minority candidates are particularly encouraged to apply.

MECHANISM OF SUPPORT

This RFA will use the NIH Graduate Training Programs Grant (T01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicants. The period of support is one year.

It is expected that up to four awards will be made, each award not to exceed \$117,000 total costs per year. A disciplinary school or department in a single institution may submit multiple faculty scholar applications if each application focuses on a different priority area. In considering multiple requests, however, applicants should be mindful of the necessity for NIMH funding decisions to be based at least in part on disciplinary and geographic distribution considerations. Awards will be limited to one per professional school or academic department for each priority area.

Payback

Any graduate or postgraduate trainee, including a faculty scholar awardee, in psychology, psychiatry, nursing, social work, or marriage and family therapy who receives support in an established training program designed to be for a period of 180 days or more under an NIMH clinical training grant must pay back through a period of obligated service equal to the length of support. The period of support need not be continuous. Any support received for any period of time under previous NIMH clinical training grants, if the stipend was awarded on or after September 1, 1981, will count toward this total. The conditions of the obligated service requirement are set forth in the 42 Code of Federal Regulations Part 64a.

FUNDS AVAILABLE

Applications submitted in response to this announcement will compete for approximately \$500,000 in grant funds that has been set aside for this purpose in Fiscal Year 1992. This is a one-time announcement. The anticipated award date will be September 30, 1992.

RESEARCH OBJECTIVES

Schizophrenic Disorders

NIMH has designated schizophrenia as one of its foremost research priorities. In so doing, NIMH has recognized the enormous public health challenge posed by schizophrenia, acknowledged the immense and chronic burden borne

by people with this disorder and by their families, and made a commitment to advance rapidly our state of knowledge and clinical training with respect to this major mental illness. Faculty who are expert clinicians and researchers are needed to train additional mental health professionals who will provide services for those who are affected by this illness.

Mood, Anxiety, and Personality Disorders

Mood, anxiety, and personality disorders rank among the most serious and pervasive public health problems in the United States. Depressive disorders affect one in twenty American adults in any one-month period and the figures for anxiety are even higher. Most persons with depression also have an anxiety disorder. Although effective psychotherapeutic and pharmacological treatments exist, research shows that most depressed and anxious persons are undiagnosed, often untreated, and frequently treated inappropriately. Improved service provider training is needed and possible. Faculty with clinical and research expertise in these disorders are needed to train service providers and researchers.

Severe Mental Disorders of Children and Adolescents

Major efforts are needed to increase understanding of the causes and determinants of child and adolescent psychopathology, determine the effectiveness of biologic, psychotherapeutic, and social treatments, develop more effective service delivery systems, and enlarge our cadre of qualified, committed researchers and clinicians. The critical shortage of mental health professionals trained to diagnose, treat, and rehabilitate children and adolescents with severe mental disorders requires focused clinical and research training programs.

Mental Disorders of the Aging

Risk factors for mental disorder multiply through old age along such dimensions as physical limitation, social disruption, and psychological loss; many surveys have shown increases in the prevalence of symptoms of depression, in Alzheimer's disease and other dementing disorders, and in behavioral problems such as sleeplessness, agitation, and confusion that are disruptive to established patterns of family and community life. Faculty leadership to establish research and training programs in geriatric mental health is extremely limited; growth in this area represents a significant priority in NIMH.

In addition to these four priority areas, scholars are encouraged to focus on specific subgroups that continue to be underserved. The problem of co-morbidity (i.e., the mentally disordered who are also substance abusers) is recognized as a challenge since 32 percent of persons with mood disorders and 47% of persons with schizophrenia also have an addictive disorder. Other subgroups include minority and rural populations.

Another area of interest is the development of strong ties between academic mental health training institutions and public mental health facilities. These systems offer a rich opportunity for enhanced services in the public sector. Thus, NIMH strongly encourages faculty scholar proposals that demonstrate collaborative linkages between academic centers and those public mental health service settings where the seriously mentally ill receive treatment.

APPLICATION PROCEDURES

Application kits (PHS 398, rev. 10/88) are available from the Education and Training Branch, Division of Clinical Research, NIMH (see below) and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441. The RFA label must be affixed to the bottom of the face page of the original copy of the application. Failure to use this label could result in delayed processing of your application such that it will not reach the review committee in time for review.

As noted in the RFA, the original and four copies of the application should be sent to the Division of Research Grants, NIH, Room 240, 5333 Westbard Avenue, Bethesda, MD 20892. Because of the short time available for reviews noted below, one additional copy should also be sent directly to the NIMH Division of Extramural Activities, Room 9C-02, Parklawn Building. The deadline date for this submission is April 24, 1992.

REVIEW CONSIDERATIONS

A dual review system is used to ensure expert, objective review of the quality of applications. Initial peer review for educational and technical merit is by Initial Review Groups (IRGs) comprised of non-Federal mental health authorities. Final review is by the National Advisory Mental Health Council whose review may be based on policy as well as educational and technical merit.

AWARD CRITERIA

The following basic criteria will be used in making award decisions:

- o quality of the overall application as determined during the review process
- o quality of public-academic linkages provision
- o where appropriate, balance among disciplines, geographic locations, and priority areas
- o availability of funds

INQUIRIES

Application kits and staff consultation on all aspects of relation to schizophrenic disorders, mood disorders,

and severe mental disorders of children and adolescents, with the exception of specific research issues bearing upon these populations, are available from:

Lemuel B. Clark, M.D., Chief
Education and Training Branch
Division of Clinical Research
Telephone: (301) 443-5850

Further information on fiscal matters, including payback requirements, is available from:

Mr. Stephen Hudak
Chief, Grants Management Section
Grants Management Branch
Telephone: (301) 443-4456

The mailing address for all of the above is:

National Institute of Mental Health
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 93.244. Applications will be accepted under the authority of Section 303 of the Public Health Service Act (42 U.S.C. 242a); 42 CFR Part 64. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or review by a Health Systems Agency.

MENTAL HEALTH INSTITUTIONAL CLINICAL TRAINING GRANTS: PROFESSIONAL TRAINING ADDRESSING SEVERE MENTAL DISORDERS

NIH GUIDE, Volume 21, Number 7, February 21, 1992

RFA AVAILABLE: MH-92-07

P.T. 44; K.W. 0720005, 0715095, 0715129

National Institute of Mental Health

Applications Receipt Date: April 24, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES BELOW.

PURPOSE

The purpose of the National Institute of Mental Health (NIMH) clinical training program is to enhance the quality and effectiveness of services to persons with major mental disorders. Insufficient numbers of well-trained mental health professionals are available to serve (1) severely and persistently mentally ill adults, e.g., adults with schizophrenic disorders or mood disorders, including homeless persons with these disorders; (2) seriously emotionally disturbed children and adolescents; (3) elderly persons with mental disorders; (4) individuals with mental disorders in rural areas; (5) racial/ethnic minorities with mental disorders.

This program is designed to recruit and prepare mental health professionals in the core mental health disciplines of social work, psychiatric nursing, psychology, psychiatry, and marriage and family therapy who are well trained and experienced in modern mental health diagnostic, treatment, and rehabilitation techniques, research methodologies and findings, and the delivery of care within community-based systems.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000". PHS urges applicants to submit work plans that address specific objectives of "Healthy People 2000." Potential applicants may obtain a copy (Full Report: Stock Number 017-001-00474-0 or Summary Report: Stock Number 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone: 202-783-3238).

ELIGIBILITY REQUIREMENTS

Accredited and/or approved departments/divisions in the mental health core disciplines of psychiatric nursing, psychiatry, psychology, social work, and marriage and family therapy in colleges or universities of the United States, including territories and possessions, are eligible to apply. Multidisciplinary applications are encouraged. Applications may be for predoctoral and/or postdoctoral training in any of these fields.

MECHANISM OF SUPPORT

This RFA will use the NIH Graduate Training Programs Grant (T01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicants. The period of support is limited to three years.

Payback Provisions

Any trainee who receives a clinical traineeship in psychology, psychiatry, psychiatric nursing, social work, or marriage and family therapy, in an established training program, designed to be for a period of 180 days or more under an NIMH clinical training grant, must pay back a period of obligated service equal to the length of the traineeship.

FUNDS AVAILABLE

Applications submitted in response to this announcement will compete for approximately \$800,000 in grant funds which has been set aside for this purpose in Fiscal Year 1992. However, since this program is proposed in the President's FY 1992 budget for phase down over 3 years, no guarantee can be provided for funding beyond the first year. The anticipated award date will be September 30, 1992. It is expected that up to 10 to 16 awards will be made, each award not to exceed \$80,000 total costs per year.

OBJECTIVES

Applicants under this RFA must focus in depth on one or more of the priority populations described below. Programs must demonstrate that they incorporate the latest diagnostic and treatment procedures, as well as the latest relevant research findings. The priority service populations for this RFA are:

- o Severely and Persistently Mentally Ill Adults
- o Children and Adolescents with Mental Disorders
- o Elderly with Mental Disorders
- o Mentally Ill in Rural Areas
- o Racial/Ethnic Minorities with Mental Disorders

Additional cross-cutting priorities are linkages between academic programs and State/community service systems, i.e., public-academic linkages (PAL) and linkages with clinical researchers and research trainers. All programs must also show evidence that curriculum content and clinical field experiences address ethnic and cultural issues.

APPLICATION PROCEDURES

Applications kits (PHS 398, Rev. 10/88) containing the necessary forms and Special Instructions may be obtained by contacting the Education and Training Branch staff. Applicants must use the Special Instructions included in the application kit, specifically designed for this NIMH Institutional Clinical Training Grant program.

Applications should include a brief description of the applicant educational institution and, where appropriate, associated service and clinical research settings, including background, history, programmatic focus, organization, resources, personnel, and record of educational/service/research linkage achievements.

As noted in the RFA, the original and four copies of the application should be sent to the Division of Research Grants, NIH, Room 240, 5333 Westbard Avenue, Bethesda, MD 20892. Because of the short time available for reviews noted below, one additional copy should also be sent directly to the NIMH Division of Extramural Activities, Room 9C-02, Parklawn Building. The deadline date for this submission is April 24, 1992. The RFA label must be affixed to the bottom of the face page of the original copy of the application. Failure to use this label could result in delayed processing of your application such that it will not reach the review committee in time for review.

REVIEW CONSIDERATIONS

A dual review system is used to ensure expert, objective review of the quality of applications. The first step, peer review for educational and technical merit, is by primarily non-Federal experts comprising Initial Review Groups. Notification of the review recommendations will be sent to the applicant after the initial review. The final review is by the National Advisory Mental Health Council. Only applications recommended for approval by the Council may be considered for funding.

INQUIRIES

Staff consultation on clinical training grants, as well as application kits and Special Instructions, is available from:

Lemuel B. Clark, M.D., Chief
Education and Training Branch
Division of Clinical Research
Telephone: (301) 443-5850

Further information on fiscal matters, including payback requirements, is available from:

Mr. Stephen Hudak
Chief, Grants Management Section
Grants Management Branch
Telephone: (301) 443-4456

The mailing address for all of the above is:

National Institute of Mental Health
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 93.244. Applications will be accepted under the authority of Section 303 of the Public Health Service Act (42 U.S.C. 242a); 42 CFR Part 64. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or review by a Health Systems Agency.

MENTAL HEALTH INSTITUTIONAL CLINICAL TRAINING GRANTS: PROFESSIONAL TRAINING FOR RACIAL/ETHNIC MINORITY AND DISADVANTAGED STUDENTS

NIH GUIDE, Volume 21, Number 7, February 21, 1992

RFA AVAILABLE: MH-92-08

P.T. 44, FF; K.W. 0720005, 0715095, 0715129

National Institute of Mental Health

Applications Receipt Date: April 24, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES BELOW.

PURPOSE

Racial and ethnic minorities are expected soon to become one quarter of the United States population. Projections are that the need for mental health services will rise proportionately, particularly in the public sector where most minority persons are served. There is increasing evidence also that when minority persons require mental health services they most often seek mental health professionals of a race or ethnicity similar to their own or choose settings staffed by mental health professionals who demonstrate responsiveness to their needs. Currently minorities represent less than 10 percent of mental health professionals. The need to increase the numbers of racial and ethnic minority mental health professionals is clear so that they may not only serve their own communities but also contribute to improving the overall quality of the mental health system by promoting its responsiveness to the unique needs of culturally diverse groups.

This program is designed to support recruitment and education of racial/ethnic minority and disadvantaged students to become professionals in the core mental health disciplines of social work, psychiatric nursing, psychology, psychiatry, and marriage and family therapy. The term "minority" in this announcement refers to Blacks, Hispanics, Asian/Pacific Islanders (including Native Hawaiians and Samoans), and American Indians/Alaska Natives. The definition of disadvantaged students is left to the applicant institution which must justify it. It could include the hearing impaired or those with other handicapping conditions but would not extend to individuals whose sole disadvantage is economic.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000". PHS urges applicants to submit work plans that address specific objectives of "Healthy People 2000." Potential applicants may obtain a copy (Full Report: Stock Number 017-001-00474-0 or Summary Report: Stock Number 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone: 202-783-3238).

ELIGIBILITY REQUIREMENTS

Accredited and/or approved departments/divisions in the mental health core disciplines of psychiatric nursing, psychiatry, psychology, social work, and marriage and family therapy in colleges or universities of the United States, including territories and possessions, are eligible to apply. Multidisciplinary applications are encouraged. Applications may be for predoctoral and/or postdoctoral training in any of these fields.

MECHANISM OF SUPPORT

This RFA will use the NIH Graduate Training Programs Grant (T01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicants. The period of support is limited to 3 years.

Payback Provisions

Any trainee who receives a clinical traineeship in psychology, psychiatry, psychiatric nursing, social work, or marriage and family therapy, in an established training program, designed to be for a period of 180 days or more under an NIMH clinical training grant, must pay back a period of obligated service equal to the length of the traineeship.

FUNDS AVAILABLE

Applications submitted in response to this announcement will compete for approximately \$800,000 in grant funds which has been set aside for this purpose in Fiscal Year 1992. However, since this program is proposed in the President's FY 1992 budget for phase down over three years, no guarantee can be provided for funding beyond the first year. The anticipated award date will be September 30, 1992. It is expected that up to 10 to 16 awards will be made, each award not to exceed \$80,000 total costs per year.

OBJECTIVES

The National Institute of Mental Health (NIMH) offers to racial/ethnic minority and disadvantaged students clinical training programs that are intended to enhance the quality and effectiveness of services to persons with major mental disorders. Applicants under this RFA must focus in depth on one or more of the priority populations described below. Programs must demonstrate that they incorporate the latest diagnostic and treatment procedures and the latest relevant research findings.

The priority service populations for this RFA are:

Severely and Persistently Mentally Ill Adults

Children and Adolescents with Severe Mental Disorders

Elderly with Mental Disorders

Mentally Ill in Rural Areas

Racial/Ethnic Minorities with Mental Disorders

Other cross-cutting priorities are linkages between academic programs and State/community service systems, i.e., public-academic linkages (PAL) and linkages with clinical researchers and research trainers.

APPLICATION PROCEDURES

Prospective applicants are strongly encouraged to consult NIMH staff regarding eligibility and assistance in developing applications. Applications kits (PHS 398, Rev. 10/88) containing the necessary forms and Special Instructions may be obtained by contacting the Education and Training Branch staff listed at the end of this announcement.

Applications must include a brief description of the applicant educational institution and, if appropriate, associated service and clinical research settings, including background, history, programmatic focus, organization, resources, personnel, and record of educational/service/research linkage achievements. Each application must include descriptions of

- o the pool from which minority and/or disadvantaged trainees will be recruited, recruitment strategies, selection criteria
- o goals and objectives of the training
- o curricula content that addresses ethnic and cultural issues
- o specific steps to be taken for the recruitment, retention, and graduation of minority and/or disadvantaged trainees
- o key faculty members and clinical supervisors

As noted in the RFA, the original and four copies of the application should be sent to the Division of Research Grants, NIH, Room 240, 5333 Westbard Avenue, Bethesda, MD 20892. Because of the short time available for reviews noted below, one additional copy should also be sent directly to the NIMH Division of Extramural Activities, Room 9C-02, Parklawn Building. The deadline date for this submission is April 24, 1992. The RFA label must be affixed to the bottom of the face page of the original copy of the application. Failure to use this label could result in delayed processing of your application such that it will not reach the review committee in time for review.

REVIEW CONSIDERATIONS

A dual review system is used to ensure expert, objective review of the quality of applications. The first step, peer review for educational and technical merit, is by primarily non-Federal experts comprising initial review groups. The final review is by the National Advisory Mental Health Council. Only applications recommended for approval by the Council may be considered for funding.

AWARD CRITERIA

Awards will be made on the basis of the following criteria:

- o quality of proposed education/training programs as determined by the review process
- o balance among programs directed to the priority populations, among the disciplines and, where appropriate, among geographic, especially rural, locations
- o availability of funds

INQUIRIES

Staff consultation on clinical training grants, as well as application kits and Special Instructions, is available from the following:

Lemanuel B. Clark, M.D., Chief
Education and Training Branch
Division of Clinical Research
Telephone: (301) 443-5850

Further information on fiscal matters, including payback requirements, is available from:

Mr. Stephen Hudak
Chief, Grants Management Section
Grants Management Branch
Telephone: (301) 443-4456

The mailing address for all of the above is:

National Institute of Mental Health
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 93.244. Applications will be accepted under the authority of Section 303 of the Public Health Service Act (42 U.S.C. 242a); 42 CFR Part 64. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or review by a Health Systems Agency.

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21, No. 7, Part 2 of 2
February 21, 1992

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NOTICES OF AVAILABILITY (RFPs AND RFAs)

SHORT-TERM CLINICAL TRAINING GRANTS IN DIAGNOSIS AND TREATMENT OF DEPRESSIVE DISORDERS

NIH GUIDE, Volume 21, Number 7, February 21, 1992

RFA AVAILABLE: MH-92-09

P.T. 44; K.W. 0720005, 0715072, 0745020, 0745060

National Institute of Mental Health

Letter of Intent Receipt Date: May 4, 1992

Application Receipt Date: May 19, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES BELOW.

PURPOSE

As part of its Depression Awareness, Recognition and Treatment (D/ART) program, the National Institute of Mental Health (NIMH) seeks applications for programs of short-term (not to exceed five days duration) continuing education. Each program will be carried out at several locations (minimum of six different sites per year) and will provide continuing education for primary care providers and mental health professionals. Support is available for the development, implementation, and evaluation of training programs that are designed to foster the more effective recognition, diagnosis, and treatment of major depressive disorders including manic depression and clinical depression.

HEALTHY PEOPLE 2000

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000." This RFA, Short-term Clinical Training Grants in Diagnosis and Treatment of Depressive Disorders, is related to the following priority areas: the proportion of persons with depressive disorder who receive treatment (6.7) and the increase of primary care providers who routinely review with patients the patients' cognitive, emotional, and behavioral functioning (6.13). Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock Number 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock Number 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20409-9325, telephone: 202-783-3238.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by a department of psychiatry in, or associated with, a school of medicine, or a free-standing mental health institution with an approved psychiatric residency program; a university-based department of psychology offering doctoral training in clinical psychology, or a school of professional psychology with appropriate accreditation for doctoral training in clinical psychology; a college or university school of nursing that offers a graduate program in psychiatric nursing; or a school of social work with a graduate program. Applications may be submitted only by domestic institutions.

All applicants must have experience and demonstrated capacity in the provision of continuing education tied to research on depressive disorders and must use multidisciplinary teams of trainers. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the NIH Continuing Education Grant (T15). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicants.

Terms and Conditions of Support

Period of Support: The period of support is up to three years (with a maximum of \$125,000 total costs per year), though no firm commitment can be made beyond the first year. Therefore, activities in the first year must be significant with a minimum of six programs provided at six different sites in each grant year.

Average Size of Award: It is expected that up to four awards may be made, each award not to exceed \$125,000 total (direct and indirect) costs per award in fiscal year 1992. Funds made available under this grant may not be used to replace currently existing training or other support for such training.

Direct Costs: Funds may be used only for those expenses that are directly related and necessary to carry out the project and must be expended in conformance with DHHS cost principles and conditions set forth in this document.

All budget items must be fully justified at the level requested. Grantees are expected to be familiar with and comply with applicable cost policies.

Teaching Costs: Direct cost items are allowable for teaching costs associated with these programs, i.e., personnel, consultants, materials, supplies, travel, reproduction and printing costs, rental equipment, minor equipment items, and other items that are directly related to the proposed training program and are otherwise unavailable from the institution.

FUNDS AVAILABLE

Applications submitted in response to this announcement will compete for approximately \$500,000 in grant funds that have been set aside for this purpose in Fiscal Year 1992. This is a one-time announcement. The anticipated award date will be September 30, 1992.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 4, 1992, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. Letters of intent are to be submitted to Dr. Harold Goldstein at the address under INQUIRIES.

APPLICATION PROCEDURES

Applicants are to use the form PHS 398 (rev. 9/91). Application kits are available from the Prevention Research Branch, Room 10-85, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone: 301-443-4140.

The applicant must include a description of the applying entity, relevant personnel, and training resources; a conceptualization of the training program including its goals and objectives; and a detailed description of the proposed training program including the curriculum.

REVIEW CONSIDERATIONS

A dual review system is used to insure knowledgeable, objective review of the quality of applications. Initial peer review for scientific, educational, and/or technical merit is by groups of non-Federal experts called Initial Review Groups. Final review is by the National Advisory Mental Health Council.

INQUIRIES

For further information regarding programmatic issues, including the RFA, applicants may contact:

Harold Goldstein, Ph.D.
Director of Training, D/ART Program
Prevention Research Branch
Division of Clinical Research
National Institute of Mental Health
Parklawn Building, Room 10-85
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4140

For information regarding fiscal issues, applicants may contact:

Stephen J. Hudak
Chief, Grants Management Section
National Institute of Mental Health
Parklawn Building, Room 7C-26
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4456

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 93.244. Applications will be accepted under the authority of Section 303 of the Public Health Service Act (42 U.S.C. 242a), 42 CFR Part 64. Applications submitted in response to this RFA are not subject to the intergovernmental review requirements of Executive Order 12372 as implemented through DHHS regulations at 45 CFR Part 100. Regulations at 42 CFR Part 242a and Title 445 CFR Part 74 and 92, generic requirements concerning the administration of grants, are applicable to these awards.

SHORT-TERM GRANTS FOR TRAINING MEDICAL STUDENTS IN THE DIAGNOSIS AND TREATMENT OF DEPRESSIVE DISORDERS

NIH GUIDE, Volume 21, Number 7, February 21, 1992

RFA AVAILABLE: MH-92-10

P.T. 44; K.W. 0720005, 0715072, 0745020, 0745060

National Institute of Mental Health

Letter of Intent Receipt Date: May 4, 1992

Application Receipt Date: May 19, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES BELOW.

PURPOSE

As part of the Depression, Awareness and Treatment (D/ART) Program, the National Institute of Mental Health (NIMH) seeks applications from medical schools to develop and implement training of pre-doctoral medical students in the diagnosis and treatment of clinical depression according to a basic curriculum presented in this RFA. Support is available for the detailed development of this curriculum, its implementation, and evaluation of its educational effectiveness and impact. The goal of the training is to prepare medical students to deal with depressive disorders, including major depression and bipolar disorder, as these disorders appear in medical settings.

HEALTHY PEOPLE 2000

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000." This RFA, Short-term Grants for Training Medical Students in the Diagnosis and Treatment of Depressive Disorders, is related to the following priority areas: the proportion of persons with depressive disorder who receive treatment (6.7), and the increase of primary care providers who routinely review with patients the patients' cognitive, emotional, and behavioral functioning (6.13). Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock Number 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock Number 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20409-9325, telephone: 202-783-3238.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by accredited schools of medicine and osteopathy. There is special interest in applications submitted by departments of family medicine, internal medicine, obstetrics and gynecology, and other nonpsychiatric specialties. Applications may be submitted only by domestic institutions. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the NIH Continuing Education Grant (T15). Responsibility for the planning, direction, and

execution of the proposed project will be solely that of the applicants.

Terms and Conditions of Support

Period of Support: The period of support is one year.

Average Size of Award: It is expected that up to 10 awards will be made, not to exceed \$15,000 total (direct and indirect) costs per award. Funds made available under this grant may not be used to supplement existing training or other support for such training.

Direct Costs: Direct cost items are allowable for teaching costs associated with this program including personnel, consultants, materials, supplies, reproduction and printing costs, rental equipment, minor equipment items, and other items that are directly related to the proposed training program and are otherwise unavailable from the institution. Funds are not available for tuition and other subsidies of medical students. Funds may be used only for those expenses that are directly related and necessary to carry out the project and must be expended in conformance with DHHS cost principles, the Public Health Service Grants Policy Statement, and conditions set forth in the RFA.

FUNDS AVAILABLE

Applications submitted in response to this announcement will compete for approximately \$150,000 in grant funds that have been set aside for this purpose in Fiscal Year 1992. This is a one-time announcement. The anticipated award date will be September 30, 1992.

LETTER OF INTENT

It is suggested that those who anticipate applying send a letter of intent to Harold Goldstein, Ph.D. (see INQUIRIES). This letter of intent is not binding, nor is it a necessary requirement, but the information that it contains is helpful in planning for the review of applications. Letters of intent are to be received by May 4, 1992. The letter of intent should include a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

APPLICATION PROCEDURES

Applicants are to use the form PHS 398 (rev. 9/91). Application kits are available from the Prevention Research Branch, Room 10-85, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone: 301-443-4140.

The applicant must provide a description of the applying entity, its relevant personnel, and its training resources; a conceptualization of the training program, including its goals and objectives; and a detailed description of the proposed training program, including the curriculum.

REVIEW CONSIDERATIONS

A dual review system is used to ensure knowledgeable, objective review of the quality of applications. Initial peer review for scientific, educational, and/or technical merit is by groups of non-Federal experts called Initial Review Groups. Final review is by the National Advisory Mental Health Council, that will address policy areas.

INQUIRIES

For further information regarding programmatic issues and requests for the RFA, applicants may contact:

Harold Goldstein, Ph.D.
Director of Training, D/ART Program
Prevention Research Branch
Division of Clinical Research
National Institute of Mental Health
Parklawn Building, Room 10-85
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4140

For information regarding fiscal issues, applicants may contact:

Stephen J. Hudak
Chief, Grants Management Section
Grants Management Branch
National Institute of Mental Health
Parklawn Building, Room 7C-26
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4456

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 93.244. Applications will be accepted under the authority of Section 303 of the Public Health Service Act (42 U.S.C. 242a); 42 CFR Part 64. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or review by a Health Systems Agency. Regulations at 42 CFR 242a and Title 45 CFR Part 74 and 92, generic requirements concerning the administration of grants, are applicable to these awards.

INTERMEDIATE ENDPOINTS AND THEIR MODULATION BY CHEMOPREVENTIVE AGENTS

NIH GUIDE, Volume 21, Number 7, February 21, 1992

RFA AVAILABLE: CA-92-06

P.T. 34; K.W. 0715035, 0740018, 0760002, 0760003

National Cancer Institute

Letter of Intent Receipt Date: March 25, 1992

Application Receipt Date: May 19, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications for cooperative agreements to support clinical trials which are directed toward examining the role of various chemopreventive agents and/or diet in the prevention of cancer.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Prevention Clinical Trials Utilizing Intermediate Endpoints and Their Modulation by Chemopreventive Agents, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00476-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) cooperative agreement (U01), for which substantial programmatic staff involvement of the awarding component is expected. An assistance relationship will exist between the NCI and the awardees to accomplish the objectives of the activity. The recipients will have primary responsibility for the development and performance of the activity. However, there will be government involvement with regard to (1) assistance securing an Investigational New Drug (IND) approval from the Food and Drug Administration (FDA), (2) monitoring of safety and toxicity, (3) coordination and assistance in obtaining the chemopreventive agent, and (4) quality assurance with regard to the clinical chemistry aspects of the study. The total project period for applications submitted in response to the present RFA may not exceed five years.

FUNDS AVAILABLE

Approximately \$1.5 million in total costs per year for five years will be committed to fund applications that are submitted in response to this RFA. It is estimated that three to five applications will be funded.

This level of support is dependent on the receipt of sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, awards pursuant to this RFA are also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The major objective of this solicitation is to encourage cancer chemoprevention clinical trials that utilize biochemical and/or biological markers to identify populations at risk for cancer and/or to provide intermediate endpoints that may predict later reduction in cancer incidence rates.

These studies may be developed in phases, including a pilot phase, that could proceed to a full-scale intervention. The main emphasis should be on small, efficient studies aimed at improving future research designs of chemoprevention trials, providing biologic understanding of what is happening in the trials, or providing better, more quantitative, and more efficient endpoints for these trials. After successful completion of the pilot phase (i.e., demonstrated modulation of marker endpoints by the intervention), subsequent studies

can include Phase III clinical trials involving the designated agent, the utilization of the monitoring test system, and a cancer incidence or mortality endpoint.

Investigators may apply at this time for the pilot phase or both phases. However, if the application is for the pilot phase only, the proposed study must describe its relevance to a clinical application and utilize a chemopreventive agent, marker test system, and study population that could later be the subject of a full-scale, double-blind, randomized, risk-reduction clinical trial.

STUDY POPULATION

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 25, 1992, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NCI staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Marjorie Perloff, M.D.
Chemoprevention Branch
National Cancer Institute
Executive Plaza North, Suite 201
9000 Rockville Pike
Bethesda, MD 20892-4200
Telephone: (301) 496-8563

APPLICATION PROCEDURES

The receipt date for applications is May 19, 1992. The research grant application form PHS 398 (revised 9/91) is to be used in applying for these cooperative agreements. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892, telephone 301/496-7441; or from the NCI Program Director named below.

The RFA label available in the PHS 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the title of the application, "Prevention Clinical Trials Utilizing Intermediate Endpoints and Their Modulation by Chemopreventive Agents", and the RFA number, CA-92-06, must be typed in block 2 of the face page of the application form.

Submit a signed, typewritten original of the application, including the Checklist, and four signed, exact photocopies, in one package to the Division of Research Grants at the address below. The photocopies must be clear and single sided.

DIVISION OF RESEARCH GRANTS
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At time of submission, two additional copies of the application must also be sent to:

REFERRAL OFFICER
Division of Extramural Activities
National Cancer Institute
Room 848, Westwood Building
5333 Westbard Avenue
Bethesda, MD 20892

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed (initially) by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to the RFA is an NCI program staff function. Applications will be judged to determine responsiveness to the goals and objectives of the program as described in the RFA. Applications that

are judged non-responsive will be returned to the applicant but may be submitted as investigator initiated applications at the next receipt date.

Those applications judged to be both competitive and responsive will be further evaluated for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NCI. The second level of review will be by the National Cancer Advisory Board.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Marjorie Perloff, M.D.
Chemoprevention Branch
National Cancer Institute
Executive Plaza North, Suite 201
9000 Rockville Pike
Bethesda, MD 20892-4200
Telephone: (301) 496-8563

Direct inquiries regarding fiscal matters to:

Ms. Eileen Natoli
Team Leader, DCPC
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Suite 243
9000 Rockville Pike
Bethesda, MD 20892-4200
Telephone: (301) 496-7800 Ext. 56

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.399, Cancer Control. Awards will be made under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410, 42 U.S.C. 241, and Section 412, as amended by Public Law 99-158, 42 U.S.C. 258a-1); and administered under PHS grants policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

REPRODUCTIVE FUNCTION IN PEOPLE WITH PHYSICAL DISABILITIES

NIH GUIDE, Volume 21, Number 7, February 21, 1992

RFA AVAILABLE: HD-92-09

P.T. 34; K.W. 0413002, 0415003, 1002030

National Institute of Child Health and Human Development

Application Receipt Date: May 22, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The National Center for Medical Rehabilitation Research (NCMRR) of the National Institute of Child Health and Human Development (NICHD) invites research grant applications to develop new knowledge in the areas of reproductive physiology, anatomy, and behavior that are common to people with disabilities. The goal of this RFA is to restore, improve, and enhance reproductive function lost as a consequence of injury, disease, and congenital disorder. Basic, clinical, and applied research applications that address these areas are of high priority. Interdisciplinary collaborative projects are also encouraged that focus studies of human sexual functioning and reproductive behavior on the development of interventions and devices that will improve the quality of life in people with physical disabilities.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention goals of "Healthy People 2000," a PHS-led national activity for setting priorities. This RFA, Reproductive Function in People with Physical Disabilities, is related to the priority areas of nutrition, physical activity and fitness, heart disease and stroke, cancer, and diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone: 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign public and private non-profit and for-profit organizations such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Project support may be requested for one to five years and may be renewed according to the conventional procedures that pertain to PHS grants. The earliest anticipated award date will be September 1992.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary NIH peer review procedures.

FUNDS AVAILABLE

Applications submitted in response to this announcement will compete for approximately \$800,000 in grant money that has been made available for this purpose in Fiscal Year 1992. It is expected that four awards will be made. The number of awards depends upon the overall scientific merit of the applications and the availability of funds.

RESEARCH OBJECTIVES

Advances in medical care have resulted in a longer life expectancy and greater integration of people with physical disabilities into society. These individuals now lead independent lives and often wish to establish successful personal relationships and have children. This RFA invites scientists to submit grant applications for research into the re-establishment, improvement, and management of reproductive function in people with physical disabilities. Research is needed in the areas of sexual identity among children with disabilities, physiological and behavioral changes in sexual function as a result of the disabling process, obstetrical care and parenting issues. Research applications are solicited that will address basic, clinical, and applied research into the improvement of reproductive outcome and that will improve the quality of life for people with disabling conditions. A partial list of representative research topics is cited below to serve as a guide for applications solicited by this RFA.

- o characterize the effect of impairment of sexual function on psychosocial adaptation, emotional state, and relationships
- o characterize the effects of head and spinal cord trauma on sexual function and reproduction
- o define neuronal populations responsible for the sexual response and develop neural, hormonal, or pharmacological interventions to restore sensory and motor function involved in the sexual response
- o identify physical and behavioral factors associated with successful prosthetic use
- o examine the effects of immobility and the compromised autonomic nervous system on the vascular system, bioavailability of medications, and endocrine regulation on the individual, and how these affect fertility and the production of viable gametes
- o evaluate changes in the menstrual cycle and sexual response in women immediately post-injury and in longitudinal studies to develop and assess intervention strategies.
- o develop obstetrical protocols for the management of pregnant women with spina bifida, spinal cord injury, multiple sclerosis, and other disabilities
- o identify the cause of autonomic dysreflexia in spinal cord injured men and women and develop intervention strategies to reduce its incidence during sexual behavior and during pregnancy and delivery.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a special justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91). This application form is available in the business or grants and contracts office at most academic and research institutions and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441. The receipt deadline for applications prepared in response to this RFA is May 15, 1992. Late applications will be returned to the applicant.

REVIEW CONSIDERATIONS

Applications will be reviewed by staff of the NICHD for responsiveness to the RFA. Applications deemed non-responsive will be returned to the applicant. If an application is returned, the applicant has the option to resubmit the application to the Division of Research Grants as an unsolicited application during one of the three yearly review cycles (February 1, June 1, and October 1).

Responsive applications may be evaluated by preliminary triage in a peer review group to determine their scientific merit relative to other applications received in connection with this RFA. Applications judged to be non-competitive will be withdrawn and the applicant and the institutional business official will be notified. Those applications judged to be competitive will be further evaluated for technical and scientific merit by a review panel convened for this purpose by the Division of Scientific Review, NICHD.

Review criteria will be those used by NIH to evaluate investigator-initiated individual research grant (R01) applications.

The second level of review will be by the NICHD National Advisory Council.

INQUIRIES

Written and telephone requests for the RFA may be addressed to:

Danuta Krotoski, Ph.D.
Chief, Basic Rehabilitation Medicine Research Branch
National Center for Medical Rehabilitation Research
National Institute of Child Health and Human Development
Executive Plaza South, Room 450W
6120 Executive Boulevard
Rockville, MD 20892
Telephone: (301) 402-2242

For fiscal and administrative inquiries regarding this announcement, potential applicants may write or call:

E. Douglas Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 501
6130 Executive Boulevard
Rockville, MD 20892
Telephone: (301) 496-1303

AUTHORITY AND REGULATION

This program is described in the Catalog of Federal Domestic Assistance No. 93.929 Medical Rehabilitation Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MENTAL HEALTH CARE PROVIDER TRAINING IN HIV INFECTION AND AIDS

NIH GUIDE, Volume 21, Number 7, February 21, 1992

RFA AVAILABLE: MH-92-02

P.T. 34; K.W. 0502017, 0730020

National Institute of Mental Health

Application Receipt Date: May 22, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACTS NAMED IN INQUIRIES BELOW.

PURPOSE

The National Institute of Mental Health (NIMH) announces support for a limited number of proposals to train both traditional and nontraditional mental health care providers to address the psychological and the neuropsychiatric sequelae of AIDS and HIV infection. Since 1986, NIMH has provided support for a program to develop model educational approaches to train mental health providers in neuropsychiatric and psychosocial aspects of HIV infection and AIDS.

HEALTHY PEOPLE 2000

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a national activity for setting priority areas. This RFA, Mental Health Care Provider

Training in HIV Infection and AIDS, is related to the priority area of HIV infection, Objective 18.9. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Eligible applicants include mental health professional entities and other organizations demonstrating specialized mental health expertise in key project staff. They include a department in an academic institution or a mental health organization. Applications may be submitted by any public or private, non-profit organization such as a university, college, hospital, laboratory, units of State or local governments, and eligible agencies of the Federal Government. Women and minorities are encouraged to apply.

MECHANISM OF SUPPORT

This RFA will use the NIH Graduate Training Program Grant (T01).

FUNDS AVAILABLE

In fiscal year 1992, it is estimated that approximately \$1.4 million will be available to support approximately seven to eight new projects. However, the amount of funding available will depend on program priorities at the time of the award.

Allowable Costs: Grants are awarded directly to eligible applicants. Grants funds may be used for expenses clearly related and necessary to conduct the proposed project. All budget items must be fully justified at the level requested. Grantees are expected to be familiar with and comply with applicable cost policies.

Direct costs are allowable for teaching costs associated with this program. These include personnel, consultants, supplies, travel, reproduction and printing costs, rental equipment, minor equipment items, and other items which are directly related to the proposed training program and otherwise unavailable from the institution.

Terms and Conditions of Support

Period of Support: Support may be requested for a period of up to three years. Annual awards will be made, subject to availability of funds and progress achieved. The anticipated award date will be September 30, 1992.

RESEARCH OBJECTIVES

The goal of this program is to enhance the Nation's ability to have an impact on the HIV/AIDS epidemic through training the traditional mental health care providers and other health care workers who often are first-line providers of mental health services, such as medical students, primary care physicians, and the clergy.

Applicant are expected to propose a comprehensive training program, addressing the needs of traditional providers, other first line providers, and non-traditional providers. Training programs proposed must target at least five provider groups, and the applicant should include a plan which will train at least 1000 mental health care providers and trainees for each of the three years of the grant.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL STUDIES

In compliance with Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) policy, ADAMHA grants and cooperative agreements are required to include both women and minorities in study populations, unless compelling scientific or other justification for not including either women or minorities is provided. All clinical programs supported by ADAMHA are required to comply with this policy.

APPLICATION PROCEDURES

As noted in the RFA, the original and five copies of the application should be sent to the Division of Research Grants, NIH, Room 240, 5333 Westbard Avenue, Bethesda, MD 20892. The deadline date for this submission is April 24, 1992.

All applicants are to use the current version of the grant application form PHS-398 (rev. 9/91). Applications kits are available from:

Grants Management Branch
National Institute of Mental Health
Parklawn Building, Room 7C-05
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4414

REVIEW CONSIDERATIONS

A dual review system is used to insure expert, objective review of the quality of applications. Initial peer review for educational and technical merit is by Initial Review Groups (IRGs) comprised of non-Federal mental health authorities. Final review is by the National Advisory Mental Health Council whose review may be based

on policy as well as educational and technical merit.

Each grant is evaluated on its own merits. The RFA provides a series of criteria which will be used in the initial review.

INQUIRIES

Prospective applicants are encouraged to consult NIMH staff concerning eligibility and for assistance in developing applications. Staff consultation is available from:

Melvyn R. Haas, M.D.
Chief, Psychiatric Education Program
Division of Clinical Research
National Institute of Mental Health
5600 Fishers Lane, Room 7C-02
Rockville, MD 20857
Telephone: (301) 443-2120

General information on NIMH AIDS programs may be obtained from:

Ellen Stover, Ph.D.
Director, Office of AIDS Research
National Institute of Mental Health
5600 Fishers Lane, Room 7C-04
Rockville, MD 20857
Telephone: (301) 443-7281

Information on grants management issues can be obtained from:

Steven J. Hudak
Chief, Grants Management Section, Room 7C-23
National Institute of Mental Health
5600 Fishers Lane, Room 7C-23
Rockville, MD 20857
Telephone: (301) 443-4456

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 93.244. Federal regulations at 42 CFR Part 64, and Title 45 CFR Parts 74 and 92, generic requirements concerning the administration of grants, are applicable to this award. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or review by a Health Systems Agency.

SCIENCE EDUCATION PARTNERSHIP AWARD (SEPA)

NIH GUIDE, Volume 21, Number 7, February 21, 1992

RFA: AD-92-01

P.T. 25; K.W. 0720000, 0715129, 0404001, 0502017

Alcohol, Drug Abuse, and Mental Health Administration

Letter of Intent Receipt Date: April 1, 1992

Application Receipt Date: May 26, 1992

PURPOSE

This Request for Applications (RFA) for the Science Education Partnership Award (SEPA) is to increase adult science literacy through partnerships composed of community groups and scientists, along with others (e.g., educators) as appropriate.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) urges applicants to submit work plans that address specific health promotion and disease prevention objectives of "Healthy People 2000." Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00473-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238). Accordingly, SEPA projects may include, as appropriate, communication of prevention messages. However, these must be in the context of the relationship between science and health, SEPA applications must focus on science education. Applications that focus on health promotion and education will be considered unresponsive to this RFA. Those interested in projects in health promotion and education should apply to other programs within ADAMHA, e.g., prevention demonstration programs of the Office of Substance Abuse Prevention.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by public and private, non-profit and profit organizations, such as community groups, civic associations, parent and patient groups, health-advocacy groups, professional societies, units of State and local governments, colleges and universities. Women and minorities are especially encouraged to apply. Irrespective of the type of applicant organization, the application must demonstrate substantive involvement and a partnership relationship between scientists and one or more community groups in the planning and implementation of the proposed project.

MECHANISM OF SUPPORT

This RFA will use the grant-in-aid mechanism for education projects (R25). This RFA is a one-time solicitation. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) expects that there will be a range of activities proposed for support. Thus, the total project period for applications submitted in response to this RFA may range from one to three years, but may not exceed three years.

FUNDS AVAILABLE

The ADAMHA expects that \$750,000 to \$1 million will be available during FY 1992 to support this initiative. Subject to the receipt of a sufficient number of meritorious applications, it is expected that approximately four to seven projects will be supported. This is expected to be a highly competitive program and applicants should adhere closely to the program guidelines. Approved annual direct costs will be provided along with eligible indirect costs. Except for awards to State and local governments, grantees will be reimbursed for indirect costs at eight percent of total allowable direct costs or actual indirect costs, whichever is the lesser amount. State and local governments will receive reimbursement at the full indirect rate. The expected award date is September 30, 1992.

OBJECTIVES

Background

The President and the Nation's Governors have declared six "National Education Goals," among them that by the year 2000 "every adult American will be literate and will possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship." In a world increasingly influenced by rapid advances in science and technology, competition in the global economy and responsible exercise of civic duty require general scientific literacy. Accordingly, the President is "urging every American to continue learning throughout his or her life, using the myriad formal and informal means available to gain further knowledge and skills."

This RFA addresses needs in the area of adult scientific literacy, which is essential for understanding the contributions of science and technology to the improvement of personal and public health. For example, many adults lack understanding of behaviors that increase the risk for disease, the necessary use of animals in behavioral and biomedical research, the necessity for basic research to make progress toward improving health, and the excitement of doing research. Understanding of these concepts is particularly important with respect to mental illness and substance abuse disorders, which are still stigmatized and poorly understood by the adult public.

Program Description

1. Objectives

To help improve public science literacy, ADAMHA is continuing the SEPA Program in Fiscal Year 1992, which was initiated in FY 1991. The focus of this SEPA announcement is adult scientific literacy with respect to mental and addictive disorders. The programmatic objective is to involve established, adult community groups, local scientists, and educators in partnerships that improve adult public understanding of science. The educational objectives are:

- o to explain the scientific basis of the understanding of mental and addictive disorders, demonstrating their complex, multifactorial nature, including their biological components; and
- o to expose the adult public to the nature and methods of science.

Priority will be given to projects that focus on neuroscience and its importance in understanding mental and addictive disorders. Congress has declared the 1990s to be the Decade of the Brain, in recognition of the advances and exciting opportunities to increase dramatically the understanding of the normal human brain and its role in behavior and illness. Through such knowledge, it is hoped that better treatment and prevention strategies for mental and addictive disorders will be developed.

2. Characteristics of applications

Applications must have a substantive focus on science related to mental and addictive disorders including relevant basic research. In addition, applicants must demonstrate:

- o existence of an established partnership that, at a minimum, must include adult community groups and scientists and others as necessary for achieving program goals;

- o understanding of---and ability to convey to adults---major scientific questions and concepts related to research on mental and addictive disorders, particularly in the neurosciences;
- o ability to convey the nature and method of science and the centrality of basic research to the improvement of personal and public health with respect to mental and addictive disorders;
- o ability to identify specific types of individuals in the community who will be the targets of proposed adult science education programs;
- o ability to assess the local population's level of knowledge about the science base for understanding addictive and mental disorders and to develop strategies that meet identified needs;
- o ability to reach target populations through cooperation among relevant community resources that can help to maximize the impact of the program through involvement of, for example, leaders in business and industry, community leaders, members of school boards, groups that represent under-served populations, and representatives of the local media.
- o ability to evaluate the effectiveness of the program;
- o understanding of educational methodology, especially with respect to adult learners (therefore, partnerships should involve educators or other individuals with requisite expertise); and
- o plans to export the program, if successful, as a model for other communities, including dissemination of materials.

Applications must describe the partnership between scientists and community groups, along with others whose participation is important to accomplish objectives of the program (e.g., educators). In addition, it must define the procedures the partners will use to reach target groups in the adult community, including groups and individuals that rarely or never express interest in science or its relationship to personal and public health. The partnership must be substantive; that is, each partner must bring to the project resources, skills, and experiences that contribute clearly to the development and dissemination of accurate, useful messages conveyed through sound educational methodology. The application must specify those contributions and must indicate how the partnership will operate to ensure that the contributions of all parties are represented in project activities. Applicants also must plan to reach the target populations with procedures other than lectures alone. (Proposed projects should be multi-dimensional and not focus solely on reaching the members of one community organization or use a single approach, such as a series of public lectures by scientists.) Projects might emphasize a particular mental or addictive disorder, but applicants are encouraged to deal with such disorders in general, particularly considering the incidence of co-morbidity of mental and addictive disorders.

To gain maximum benefit from the program, priority will be given to projects that are innovative; that is, proposed projects should not simply expose more people to an extant program. Priority also will be given to projects that have the potential to be replicated for widespread use. Because of the special needs of women and minorities for accurate, science-based information related to their health, projects that address these needs are encouraged. Projects aimed at specific ethnic or racial groups must be culturally appropriate to the group.

Although SEPA projects must represent new activities and focus on science related to mental and addictive disorders, coordination with existing programs in the community to improve the public understanding of science is encouraged.

3. Types of activities

Examples of the types of activities that may be included as part of a proposed project, but are not necessarily sufficient in themselves, include:

- o Develop a series of workshops and demonstrations that help the public understand the scientific basis for risk factors of mental and addictive disorders and the research knowledge base for diagnostic procedures and treatment of these disorders;
- o Provide training, resources, and support to encourage and prepare individual biomedical/behavioral scientists to become involved in projects that educate the general public about science. This would include training of scientists in techniques for effective speaking to adults, teachers, and community organizations;
- o Assess common misconceptions about mental and addictive disorders and develop programs for the adult public that demonstrate, using examples from contemporary research, why those misconceptions are inaccurate;
- o Develop programs that help the adult public appreciate issues of scientific validity in media reports that deal with mental and addictive disorders;
- o Produce media programs and accompanying workshops that help explain the complex nature of the search for cures for mental and addictive disorders including controversies among scientists working in the same areas of research;
- o Preparing and/or presenting science education materials for the adult public. These materials may include television, radio, newspaper and magazine articles, books, experiments, computer software, and other written, electronic, or audiovisual presentations designed to educate the adult public about science. However, projects

for stand-alone media activities will not be supported. These must be tied to a broader program to engage adults in community-based activities related to educating them about the scientific understanding of mental and addictive disorders;

o Providing scientific and/or educational consultation to groups or organizations regarding activities consistent with the purposes of this announcement. Such groups may include professional organizations, educational organizations, and community groups.

Research institutions are encouraged to provide incentives from non-Federal sources to encourage scientists to participate in the SEPA program. These incentives may include the awarding of sabbaticals, time released from other duties, or special institutional recognition of those who participate in the program. Such applicants also are encouraged to use institutional funds made available as a result of the SEPA award (e.g., investigators' salaries) for purposes consistent with this award.

SPECIAL REQUIREMENTS

To promote cooperation and coordination among the grantees and to publicize and disseminate their contributions, it is expected that each year the Principal Investigators will be invited to a meeting with other SEPA awardees to present a summary of their activities. The annual meeting of SEPA awardees will be held in various cities of the United States. Therefore, plans for this activity must be included in the budget request of the application; a statement indicating willingness to participate in this activity must also be included in the application.

General Requirements

An annual progress report submitted as part of each noncompeting continuation application must be filed with the grants management officer of the awarding institute. Reports should summarize the goals, methods, and results of the activity undertaken. It should also be accompanied by at least two copies of any materials intended for dissemination developed as part of the SEPA project.

Grant funds may be used for expenses clearly related to and necessary for the conduct of projects in adult science literacy, including direct costs that can be specifically identified with the project, and indirect costs as specified in the Funds Available section. Direct-cost expenses must be itemized and justified for each year of the proposed project.

The general requirements cited above represent only a portion of applicable Public Health Service policy under which SEPA awards will be administered. All awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 90- 50,000 (Rev.) October 1, 1990, as subject to regulations 45 CFR Part 74 "Administration of Grants."

LETTER OF INTENT

Prospective applicants are encouraged to submit a letter of intent, by April 1, 1992, that includes a descriptive title of the proposed project, the name, address, and telephone number of the Principal Investigator (project director), the names of other key personnel and the participating institutions, and the number and title of the RFA in response to which the application is being submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of the subsequent application, the information that it contains is extremely helpful in planning for the review of applications. It allows staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

Send the letter of intent to:

Ms. Eileen O'Keefe
Assistant Director, Office of Science Education
Alcohol, Drug Abuse, and Mental Health Administration
5600 Fishers Lane, Room 13-103
Rockville, MD 20857
Telephone: (301) 443-0910

APPLICATION PROCEDURES

The Application for Public Health Service Grant form PHS 398 (revised 9/91) is to be used in applying for these grants. These forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 496-7441. Applicants must follow the instructions provided in the PHS 398 kit and the special instructions that follow:

Application Face Page - Item 2 - Check the box marked "YES". Insert the RFA number AD-92-01 and the RFA title "ADAMHA Science Education Partnership Award."

Bottom of Face Page - Affix the RFA label in form PHS 398 to the bottom of the original copy of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review.

SECTION 2

Research Plan - This part of the application must provide information sufficient to allow the reviewers to assess the merit of the project in terms of the stated Review Criteria. In lieu of the format and information requested for the Research Plan in the instructions for the PHS 398, it is suggested that the information be provided in the following format:

Goals and Objectives - Identify the specific goals to be achieved.

Project Plan - Describe the partnership that has been or will be formed, and the qualifications of its member organization(s) and key personnel. Indicate clearly the roles of the scientific, community group, and other partners in the planning and the conduct of the project. Clearly identify the target audience(s) and document the need for the proposed project including data and other information specific to the audience(s). Explain why the particular strategy was chosen. Describe in detail the activities proposed and how they will accomplish the stated goals of the program. Also, describe the specified objectives and the types of scientific concepts or information to be included in educational activities for the target population(s). Give quantitative estimates of numbers of members of the general public to be reached, and specify the number and types of any educational materials to be prepared. For the latter, describe why existing materials or activities are not satisfactory. Include dissemination plans for the project's results or materials prepared and address the potential for replication of the project.

Institutional Commitment - List the financial and/or in-kind commitments from the members of the partnership and provide evidence of the applicant institution's commitment to achieve the project goals. Appropriately countersigned letters of commitment from various agencies, groups, or persons whose cooperation is critical to the success of the project must be included. These letters must be included under the headings "Consultants/Collaborators" and/or "Consortium/Contractual Arrangements" as appropriate in the application form. Although these letters will not count toward the page limit for the Research Plan of the application, applicants are cautioned to include in this section only those letters relating to critical elements of the proposed partnership. Other letters in support of the proposed project may be included in the Appendix of the application (refer to the instructions for the PHS 398 for further information about Appendix material).

Administrative Plan - Describe the mechanisms to be used to organize and manage the project. Also, provide a schedule with milestones for carrying out all project activities.

Evaluation Plan - ADAMHA will support only projects that have a well-developed evaluation plan. As part of the screening and review processes, applications will be examined for the presence of a defined evaluation component. Applications that have a clearly inadequate evaluation plan will be judged to be incomplete and will be returned without further review.

The evaluation plan must address both the programmatic and educational objectives of this SEPA announcement; that is, the effectiveness of the partnership and the effectiveness of the educational messages. Applicants should have appropriate evaluation expertise on their staffs, or should make arrangements for obtaining such consultation to assist in developing and implementing the evaluation plan. The allocation of monies for evaluation must be consistent with the complexity of the proposed project and must provide for planning and implementation of the evaluation from the beginning of the project through completion.

Submit the signed, typewritten original of the application, including the Checklist, and four signed, exact photocopies, in one package to:

National Institutes of Health
Division of Research Grants
Westwood Building, Room 240
Bethesda, MD 20892**

At time of submission, applicants are requested to submit one additional copy of the application to:

Ms. Eileen O'Keefe
Assistant Director, Office of Science Education
Alcohol, Drug Abuse, and Mental Health Administration
5600 Fishers Lane, Room 13-103
Rockville, MD 20857
Telephone: (301) 443-0910

Applications must be received by the Division of Research Grants no later than May 26, 1992. To ensure against carrier delays, retain a legible proof-of-mailing receipt from the carrier dated no later than one week prior to the receipt date. APPLICATIONS RECEIVED AFTER THIS DATE WILL BE RETURNED TO THE APPLICANT.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness and responsiveness to the RFA, including the programmatic focus on adult scientific literacy and the educational focus on the scientific aspects of mental and addictive disorders, the required participation of scientists and community groups, and the inclusion of a defined evaluation component. Incomplete or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive will be evaluated for educational and scientific/technical merit, in accordance with the criteria stated below, by an appropriate peer review group convened by the ADAMHA. The second level of review will be provided by an appropriate National Advisory Council.

Review Criteria

The following criteria will be used in the initial review of applications:

1. Significance:

- o The importance of the specific educational goals to be achieved for the identified target population(s);
- o The degree to which the proposed project is likely to serve as a model for other organizations engaged in similar activities; and
- o Evidence that the proposed project will fill a current void or unmet need in the target community.

2. Merit of the approach:

- o The degree of innovation in the proposed project; for example, the degree to which the project establishes new types of partnerships, presents information to the public in new ways, or reaches audiences not traditionally reached with science-related information;
- o The educational merit of the proposed project; for example, the degree to which the material chosen for presentation is likely to help the adult public understand the scientific basis of mental and addictive disorders;
- o Appropriateness of the proposed approach to adult science education and the target population(s); for example, the degree to which the suggested approach reflects current knowledge about science education and adult learners, as well as appropriateness to the needs of specific types of individuals in the community; and
- o Extent to which plans reflect relevant and current scientific knowledge relating to mental and addictive disorders.

3. Feasibility:

- o The ability to accomplish the objectives of the project using the plans and resources described in the application;
- o Evidence that a functioning, relevant partnership exists;
- o The contribution of each partner and the degree of cooperation among scientists, community groups from the target populations who will plan and conduct the project, and other partners (such as educators);
- o Adequacy of the applicant's plan to evaluate the effectiveness of the project. The evaluation must address the effectiveness of the project in meeting both the programmatic and educational objectives of the SEPA program;
- o Adequacy of the applicant's plans to document and disseminate the model developed under the SEPA;
- o Appropriateness and adequacy of the proposed budget.

4. Personnel and resources:

- o Qualifications of the proposed project personnel, including the Principal Investigator (project director), scientists, community-group leaders, educators, and others to design and conduct the proposed project. For example, the application should demonstrate that the project personnel understand the science base of mental and addictive disorders; can work in a partnership to translate that information and the nature and methods of science for the adult public; and can deliver the educational messages effectively to the intended audience(s);
- o Suitability of the proposed applicant and cooperating organizations' facilities, resources, experience in similar activities, and commitment to achieve the specific goals of the proposed project;
- o Strength of institutional commitment as evidenced by provision of institutional resources, such as office and workshop space, computer facilities, and administrative and technical support services; and
- o Adequacy of plans to institutionalize the program, if successful, after cessation of ADAMHA support.

AWARD CRITERIA

In making funding decisions, the ADAMHA will consider: scientific, educational, and technical merit as determined by peer review; relevance to mental and addictive disorders; program balance among various types of projects; geographic distribution in the United States and its territories; and/or management capability for financial stewardship of Federal funds. Special consideration also will be given to applications with a specific focus on reaching minority and/or female populations. Priority will be given to projects that include scientists involved in research on mental and addictive disorders. Because of limited funds, the ADAMHA will

assign priority to those applicants not currently receiving SEPA support from ADAMHA or the National Institutes of Health.

INQUIRIES

Written and telephone inquiries regarding this RFA are encouraged, and should be directed to Ms. Eileen O'Keefe at the address and telephone number listed above.

Direct inquiries regarding fiscal matters to:

Bruce Ringler
Grants Management Office
National Institute of Mental Health
5600 fishers Lane, Room 7C-15
Rockville, MD 20857
Telephone: (301) 443-3065

Schedule

Letter of Intent: April 1, 1992
Application Receipt Date: May 26, 1992
Initial Review: June - August 1992
Secondary Review: September 1992
Anticipated Award Date: September 30, 1992

AUTHORITY AND REGULATIONS

ADAMHA awards are under the authority of Section 301 of the Public Health Service Act, as amended, (42 U.S.C. 24). All awards will be administered under PHS grant policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

MEDICAL REHABILITATION RESEARCH

NIH GUIDE, Volume 21, Number 7, February 21, 1992

PA NUMBER: PA-92-42

P.T. 34; K.W. 0415001, 0415002, 0415003, 0765035, 0740070

National Institute of Child Health and Human Development

PURPOSE

The National Center for Medical Rehabilitation Research (NCMRR) of the National Institute of Child Health and Human Development (NICHD) invites qualified researchers to submit grant applications for research on restoring, replacing or enhancing the function of children and adults with disabilities. Medical rehabilitation research is directed towards restoration and improvement of functional capability lost as a consequence of injury, disease and congenital disorder. The mission of the NCMRR is to improve the ability of medical rehabilitation to restore or improve function through research on: (1) functional problems associated with diminished mobility, (2) body systems response to lost function, (3) adaptive behavior systems modifications to functional loss, (4) treatment intervention effectiveness in restoring function, (5) assistive devices that replace or enhance function, and (6) outcome measurement systems that provide an integrative method for tracking functional change over time in many different domains.

This research includes basic science studies related to the pathophysiologic mechanisms and processes underlying functional loss. Basic and clinical studies of the physical impairment that reduces function are included in the science of medical rehabilitation. Fundamental knowledge of functional development, change in functional capacity during development, and alteration of functional abilities post injury or disease is a focal point of medical rehabilitation research. The individual's adaptive and maladaptive behavioral responses to a physical impairment and functional change are the subject of a wide variety of basic, clinical and applied studies. The societal impact, both positive and negative, of how persons with disabilities adjust to the demands of culture (e.g., family, work, support systems) and to natural and man-made environmental barriers frames the outcome success or failure of medical rehabilitation programs.

These studies of assisted recovery from or adaptation to functional loss are conducted by researchers from a wide variety of scientific disciplines such as specialists in physical and rehabilitation medicine (physiatry), neurology, pediatrics, urology, orthopedics, neurosurgery, nursing, physical therapy, occupational therapy, rehabilitation psychology, sociology, demography, epidemiology, biomedical engineering, rehabilitation engineering, orthotists, prosthetists, and other related health professionals. In addition, the basic sciences contribute to understanding mechanisms and processes fundamental to functional recovery. These disciplines include genetics, molecular biology, neurosciences, physiological sciences and other physical sciences. Both intradisciplinary and interdisciplinary research are needed and encouraged.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention goals of "Healthy People 2000," a PHS-led national activity for setting priorities. This program announcement, Medical Rehabilitation Research, is related to the priority areas of nutrition, physical activity and fitness, heart disease and stroke, cancer, and diabetes and chronic disabling conditions. Potential applicants may a copy of "Healthy People 2000" (Full Report: No. 017-001-474-0, or Summary Report: Stock No 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone: 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged. Additional eligibility requirements must be met for institutional training grants (T32), fellowships (F32, F33), and career development awards (K series).

MECHANISMS OF SUPPORT

The mechanisms available for support of this program announcement are: Individual Research Grants (R01), First Independent Research Support and Transition (FIRST) Awards (R29), Program Project Grants (P01), Research Career Development Awards (K04), The Academic/Teacher Awards (K07), The Clinical Investigator Award (K08), The Physician Scientist Award (K11), National Research Service Award Institutional Training Grants (T32), and Individual Fellowships (F32, F33).

RESEARCH OBJECTIVES

Background

Between 35 million and 43 million Americans, or 1 in 7, have a disability. Almost four percent of the U.S. population are unable to carry out the major activity of their age group because of severe disabilities. An additional six percent of the population are restricted in their major activity, and another 4 percent are limited in other types of activity. The NCMRR provides an opportunity for scientists to conduct research on the functional changes resulting from illness, injuries, and developmental processes that begin before birth and continue until the last stages of life. The emphasis will be on health-related improvement in human functioning at the pathophysiological, physical impairment, functional impairment, disability, and societal impact levels of analysis. Explicitly included are studies of the application of new knowledge to the development of medical, behavioral, psychological, social, and technological interventions designed to optimize functioning after impairment. Research of interest would extend from the molecular level to the functioning of individuals in their physical and social environment.

Scope

The NCMRR of the NICHD seeks research project, research training, fellowship, and research career award grant applications for the study of medical rehabilitation. This is not a one-time invitation for applications, but rather a continuing call for research on this topic. Many research issues fall within the scope of this announcement. Basic, clinical, and applied research is encouraged through intervention strategies, measurement strategies, and the development of assistive devices to improve the knowledge and understanding of the medical rehabilitation process (pathophysiology, physical impairment, functional limitation, disability and societal impact) contributing to functional loss in the broad and overlapping areas of mobility, body systems, and behavioral systems. The following are offered as illustrations of appropriate topics, but applications are not be limited to these areas:

A. MOBILITY ENHANCEMENT RESEARCH IN MEDICAL REHABILITATION

1) Treatment Effectiveness

- o Effectiveness of different treatment interventions for long-term rehabilitation of patients with mobility problems resulting from cardiovascular disease, myocardial infarction, stroke, and hypertension.
- o Studies of the neuroplasticity of the nervous and muscular systems and whether or not interventions might improve the motor functioning of individuals with neuromotor deficits.
- o Research on hormonal, neurochemical, and potential pharmacological agents (such as growth hormone) that might improve the physical functioning or the mobility of individuals with disabilities.

2) Assessment and Measurement

- o Assessment of the effects of the use of mobility aids (i.e., canes, wheelchairs, prosthetics, and orthotic devices) on the muscles and joints.
- o Assessment of the potential physiological and metabolic benefits of varying the means and modes of mobility for people with impaired mobility.
- o Identification and quantification of the factors and mechanisms involved in performing important motor tasks

such as walking, ascending stairs, reaching, sitting, and crouching.

- o Improving the analytical tools for evaluating the performance of work-related tasks.

3) Assistive Devices

o Development of mechanical and electrical devices that can assist individuals with physical disabilities to control their environment, including prosthetic and orthotic equipment, mobility enhancement (wheelchairs, walkers, safety equipment for transportation vehicles), remote control of home and work place appliances or tools, and recreational equipment for use in family, school, and community settings.

o Development and testing of devices and/or techniques designed to teach, supplement, replace or restore communicative and language functions (e.g., gesturing, listening, speaking, reading, and writing) of individuals with physical disabilities including alternative forms of communication (e.g., computer-assisted speech output, speech substitution), and/or environmental control systems for home, school, and work.

o Development of devices and techniques for the mechanical testing of tissue properties under physiologically representative conditions.

o Evaluation of the utility, functional impacts, and dependability of assistive devices.

B. BEHAVIORAL SYSTEMS RESEARCH IN MEDICAL REHABILITATION

1) Treatment Effectiveness

o Development of skill-training and educational program products and therapeutic techniques that supplement, replace, or restore the functional social, cognitive, adaptive, and motor abilities of individuals who are physically disabled.

o Development of: behavioral techniques for improvement of cognitive function (e.g., academic training), motor skills (e.g., mobility difficulties, bowel and bladder control, feeding, and dressing), the decrease or elimination of destructive behaviors (e.g., self abuse, aggression, hyperactivity) for individuals with disabilities.

o Studies of the differential between the functional capacity of older adults with disabilities and their actual level of performance.

2) Assessment and Measurement

o Development of data collection and surveillance systems necessary to generate epidemiologically sound evidence of the incidence and prevalence of impairments, functional changes, and disabilities in different societal contexts, and the conduct of such studies.

o Development and testing of theoretical formulations of the determinants of impairments, functional changes, and disabilities and the progression leading from impairment to societal impact.

o Assessments of patterns and models of care in terms of their impact on the quality of life of people with disabilities.

o Rehabilitation assessment of persons with disabilities who are losing function due to the aging process.

3) Assistive Devices

o Development and testing of software programs for computer-assisted instruction, measurement, and assessment of cognitive, vocational, and social skill acquisition for children and adults with physical disabilities.

C. BODY SYSTEMS RESEARCH IN MEDICAL REHABILITATION

1) Treatment Effectiveness

o Methods to stimulate bone and soft-tissue growth in prosthetic devices.

o Rehabilitation research in cancer survivors such as improving treatment techniques for breast reconstruction and dealing with dysfunctions associated with breast cancer therapies (behavioral and psychological problems, vaginal dryness, hot flashes, lymphedema, and shoulder dysfunction); treatments of sensory or functional deficits induced by cancer treatments.

o Clinical intervention effectiveness in attempts to prevent or remediate adverse long-term effects of kidney transplantation, e.g., multiple organ effects, behavioral changes, vocational and social effects.

o Rehabilitation of neurophysiological dysfunction including investigation of therapies that might reduce the extent of neurologic damage caused by disease or injury, induce functional plasticity and enhance restoration of function.

o Medical rehabilitation intervention effectiveness for people with chronic lung disease.

- o Effectiveness of interventions designed to prevent or remediate the adverse long-term physical, behavioral, and social effects of asthma.
- o Treatment interventions designed to improve rehabilitation of musculoskeletal disorders.
- o Treatments to maintain and improve integumentary integrity.

2) Assessment and Measurement

- o Assessment and measurement of joint mechanics and pathophysiology, musculoskeletal physiology and plasticity, interaction of musculoskeletal impairments, and the mechanisms governing muscle and bone development in the presence of normal and abnormal neural function.
- o Development of clinical tools for the quantitative assessment of muscle function, mobility, and postural control.
- o Development of quantitative measures for assessing and comparing the functional capacity to carry out routine tasks and the level of performance achieved in doing so.
- o Development of procedures and standardized protocols for determining sites of fatigue in the neuromotor systems in people with and without impairments and disabilities.

3) Assistive Devices

- o Devices to improve measurement of joint mechanics and pathophysiology, musculoskeletal physiology and plasticity, interaction of musculoskeletal impairments, and the mechanisms governing muscle and bone development in the presence of normal and abnormal neural function.
- o Development of durable waterproof, life-like cosmesis and alternative prosthetic covers.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

National Institutes of Health (NIH) policy is that applicants for NIH clinical research grants will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study. Special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions that disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial or ethnic group together with a rationale for its choice. In addition gender and racial or ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included on the grant application form PHS 398 in Section 2, A-D of the research plan and summarized in Section 2, E, (Human Subjects).

Applicants are urged to carefully assess the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial or ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies on etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials. The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissue from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, applicants must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed and the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding

components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applicants are to use the research project application form PHS 398 (revised 9/91), for the R01, R29, P01, K04, K07, K08, K11 and T32 applications. On line 2 (Response to Specific Program announcement) on the face page of the application, type: "Medical Rehabilitation Research, PA-92-42."

Applicants are advised also to review the appropriate guidelines for the various funding mechanisms for unique features of each mechanism: First Independent Research Support and Transition (FIRST) Award (R29), September 23, 1991; NIH Research Career Development Award (K04), June 1991; Clinical Investigator Award (K08), October 1991; Physician Scientist Award (K11), June 1991; and National Research Service Awards Institutional Training Grants (T32), October 1990. These publications are available at the applicant's institutional Application Control Office and from the Office of Grants Inquiries, Division of Research Grants, NIH (telephone 301-496-7441).

Because the PHS 398 form is designed primarily for the traditional R01 application, several sections, outlined on the instruction sheet, must be modified and expanded to provide the additional information required for a P01 or K07. Applicants for the P01 should use the application format as described in the NICHD pamphlet, Program Project Guidelines, 1991, that may be obtained from the contacts listed under INQUIRIES. Applicants for the K07 should also obtain guidance from the contacts listed under INQUIRIES.

Fellowship applications (F32 and F33) must be submitted on the Application for Public Health Service Individual Service Award (PHS 416-1). If the applicant is a noncitizen, a notarized statement of permanent residence must accompany the application. Applicants must submit with the application at least three letters of reference.

Receipt dates for Research Project Grants, Career Development Award, and FIRST Award applications are February 1, June 1, and October 1 of each year. The individual National Research Service Award applications are accepted January 10, May 10, and September 10. Institutional training grant applications are accepted once each year, January 10.

If using the PHS 398, submit the original application and six copies to the following address. If using the PHS 416, submit the original application and two copies to:

Grant Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

All applications will be received by the Division of Research Grants (DRG), NIH. Research project grant (R01 and R29) applications, fellowships (F32, F33) and research career development awards (K04) will be reviewed for scientific and technical merit by an appropriate study section in the Division of Research Grants. All other applications will be reviewed by an appropriate institute review group. The initial review for scientific and technical merit will be by a review group composed mostly of nonfederal scientific consultants (study section). Secondary review will be by the appropriate national advisory council. The review criteria customarily employed by the NIH PHS for applications will prevail. The specific criteria for each mechanism are described fully in the publications listed in APPLICATION PROCEDURES.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Researchers considering an application in response to this announcement are encouraged to discuss the project and the range of grant mechanisms available with NCMRR staff listed below in advance of formal submission.

Direct inquiries regarding programmatic issues to:

Louis A. Quatrano, Ph.D.
Chief, Applied Medical Rehabilitation Research Branch
National Center for Medical Rehabilitation Research
National Institute of Child Health and Human Development
Executive Plaza South, Room 450W
6120 Executive Boulevard
Rockville, MD 20852
Telephone: (301) 402-2242

or

Danuta Krotoski, Ph.D.
Chief, Basic Medical Rehabilitation Research Branch
National Center for Medical Rehabilitation Research
National Institute of Child Health and Human Development
Executive Plaza South, Room 450W
6120 Executive Boulevard
Rockville, MD 20852
Telephone: (301) 402-2242

For fiscal and administrative inquiries regarding this announcement, potential applicants may write or call:

E. Douglas Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 501
6130 Executive Boulevard
Rockville Pike, MD 20892
Telephone: (301) 496-1303

AUTHORITY AND REGULATION

This program is described in the Catalog of Federal Domestic Assistance No. 93.929, Medical Rehabilitation Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ACADEMIC AWARD IN ENVIRONMENTAL/OCCUPATIONAL MEDICINE

NIH GUIDE, Volume 21, Number 7, February 21, 1992

PA NUMBER: PA-92-43

P.T. 34; K.W. 0725000, 0725020

National Institute of Environmental Health Sciences

Application Receipt Date: June 1, 1992

PURPOSE

The National Institute of Environmental Health Sciences (NIEHS) announces the third National competition for Environmental/Occupational Medicine Academic Awards (E/OMAA). The award has the dual purpose of improving the quality of environmental/occupational medicine curricula and of fostering graduate research careers in environmental/occupational medicine. For the purposes of the E/OMAA, the term environmental/occupational medicine refers to the area of medicine concerned with the development and application of knowledge directed at the diagnosis, treatment, and prevention of adverse human health effects from environmental/occupational exposures to toxic agents. This includes adverse health effects in infants, children, and adults who are at risk of developing such health problems and the reduction of preventable complications and disability in persons of all ages who have already developed such diseases.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Academic Award in Environmental/Occupational Medicine, is related to the priority area of environmental health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Only schools of medicine and osteopathy in the United States and its possessions and territories are eligible to compete for the E/OMAA. Previous awardees of the E/OMAA are not eligible.

MECHANISM OF SUPPORT

Mechanism of support for this activity will be for the K07 research career program (academic) award. The project period may not exceed five years.

RESEARCH OBJECTIVES

The NIEHS initiated the E/OMAA Program to provide a stimulus for the development of an environmental/occupational medicine curriculum in those schools that do not have one and to strengthen and

improve the environmental/occupational medicine curriculum in schools that do. Awards provide support to applicant faculty members for their educational development and for implementation or expansion of the curriculum in environmental/occupational medicine.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). The application deadline date is June 1, 1992. Application received after this date will be returned to the applicant without review.

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, MD 20892, telephone 301/496-7441. The title and number of the announcement must be typed in Section 2 on the face page of the application.

The completed original application and six legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**



REVIEW PROCEDURES

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for technical merit by a special study section convened by the appropriate ICD in accordance with the standard NIH peer review procedures. Following technical review, the applications will receive a second-level review by national advisory council.

AWARD CRITERIA

Applications will be evaluated for evidence of commitment by both the sponsoring institution and the sponsoring department or division to the accomplishment of the objectives of the award, as well as the qualification, interest, and commitment of the candidate to undertake the responsibility for implementing a high-quality environmental/occupational medicine curriculum. Additional criteria are included in the program guidelines available from the NIEHS program staff under INQUIRIES.

INQUIRIES

The Program Guidelines for the E/OMAA award are available, and written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Annette G. Kirshner, Ph.D.
Scientific Programs Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-0488

Direct inquiries regarding fiscal matters to:

David L. Mineo
Grants Management Officer
Grants Management Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-1373

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.894. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NIH GUIDE

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Vol. 21, No. 8
February 28, 1992

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NOTICES OF AVAILABILITY (RFPs AND RFAs)

RADIOLOGIC DIAGNOSTIC ONCOLOGY GROUP IV: OVARIAN CANCER AND PEDIATRIC SOLID TUMORS

NIH GUIDE, Vol. 21, No. 8, February 28, 1992

RFA AVAILABLE: CA-92-02

P.T. 34; K.W. 0715035, 0745020, 0706030

National Cancer Institute

Letter of Intent Receipt Date: March 24, 1992

Application Receipt Date: May 26, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The Radiation Research Program (RRP), Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI), invites applications for cooperative agreements to establish a multi-institutional scientific group in order to optimize staging and follow up of pediatric solid tumors and ovarian cancer.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Radiologic Diagnostic Oncology Group IV: Ovarian Cancer and Pediatric Solid Tumors, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Non-profit and for-profit organizations and institutions, governments and their agencies, and foreign and domestic institutions are eligible to apply. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Awards will be made as cooperative agreements (U01), a funding mechanism in which substantial NCI programmatic involvement with the recipients during performance of the planned activity is anticipated. Applicants will be responsible for the planning, direction, and execution of the proposed project.

FUNDS AVAILABLE

Approximately \$800,000 in total costs per year for three years will be committed to fund applications that are submitted in response to this RFA. It is anticipated that six to eight institutions plus the Headquarters component will be funded to establish the RDOG IV.

RESEARCH OBJECTIVES

The objective of this RFA is to invite applications to perform centrally coordinated multi- institutional cooperative clinical trials to determine the most effective imaging algorithms required to stage and monitor ovarian carcinoma and pediatric solid tumors (other than those of the central nervous system). The successful applicants will form RDOG IV. The results of the RDOG IV studies should have a direct and immediate impact on patient care. Additionally, considerable health care cost saving is expected due to elimination of unnecessary diagnostic studies. Sufficient numbers of patients, including minorities and women, for significant imaging trials must be available.

Background

The Radiologic Diagnostic Oncology Group (RDOG) was formed by the NCI in September 1987. The RDOG objective is timely evaluation of current and emerging imaging modalities in the management of patients with cancer. The development of multi-institutional clinical trial groups allows for rapid patient accrual within a short period of time. This in turn ensures rapid evaluation and optimization of imaging techniques for diagnosis, staging, and serial monitoring of cancer.

The RDOG has had a significant impact on clinical research in radiology. This is the first time that multi-institutional clinical trials in diagnostic imaging have been conducted in a centrally coordinated fashion with strict quality control and analysis of cost-effectiveness. Ultimately, RDOG study findings would be useful for design of therapeutic protocols and formulating clinical and medical insurance reimbursement policy.

Since the time of its establishment, RDOG clinical research has been important for the development of optimal imaging algorithms for prostate and lung cancer (RDOG I) and pancreatic and colon cancer (RDOG II). Recently, an RFA (RDOG III) was issued to study musculoskeletal and head and neck tumor imaging, and seven additional institutions have been funded. The specific focus of this solicitation is to establish RDOG IV to study pediatric solid tumors and ovarian cancer.

SPECIAL REQUIREMENTS

The administrative and funding mechanism to be used to support these awards will be cooperative agreements (U01) between each awardee and the NCI. In a cooperative agreement there is substantial Federal programmatic involvement above and beyond the levels characteristic for traditional program management of grants. Prospective applicants are encouraged to obtain a copy of the RFA for additional information (see INQUIRIES section below).

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women and minorities are not included in the study populations, a specific and compelling justification for this exclusion must be provided. Applications that do not include women and minorities and that are without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 24, 1992, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is requested in order to provide an indication of the number and scope of applications to be reviewed.

The letter of intent is to be sent to Dr. Faina Shtern at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (revised 9/91) is to be used in applying for these grants. These forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892, telephone (301) 496-7441, and from the NCI program director named below.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, exact photocopies, in one package to the address below. The photocopies must be clear and single sided.

DIVISION OF RESEARCH GRANTS
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, send two additional copies of the application to:

REFERRAL OFFICER
Division of Extramural Activities
National Cancer Institute
Room 838, Westwood Building
5333 Westbard Avenue
Bethesda, MD 20892

Applications must be received by May 26, 1992. If an application is received after that date, it will be returned. If the application submitted in response to this RFA is substantially similar to a grant application already submitted to the NIH for review, but has not yet been reviewed, the applicant will be asked to withdraw either the pending application or the new one. Simultaneous submission of identical applications will not be allowed, nor will essentially identical applications be reviewed by different review committees. Therefore, an application cannot be submitted in response to this RFA that is essentially identical to one that has already been reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the DRG for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to the program requirements and criteria stated in the RFA is an NCI program staff function. Applications that are judged non-responsive will be returned to the applicant by the NCI, but may be submitted as investigator-initiated research grants at the next receipt date. Questions concerning the responsiveness of proposed research to the RFA may be directed to program staff listed under INQUIRIES.

If the number of applications submitted is large compared to the number of awards to be made, the NCI may conduct a preliminary scientific peer review (triage) to eliminate those that are clearly not competitive. The NCI will remove from competition those applications judged to be noncompetitive for award and notify the applicant and institutional business official.

Those applications judged to be both competitive and responsive will be further evaluated according to the review criteria stated in the RFA for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NCI. The second level of review by the National Cancer Advisory Board considers the special needs of the NCI and the priorities of the National Cancer Program.

INQUIRIES

Direct requests for the RFA and inquiries regarding programmatic issues to:

Faina Shtern, M.D.
Chief, Diagnostic Imaging Research Branch
Radiation Research Program
National Cancer Institute
Executive Plaza North, Suite 800
Bethesda, MD 20892
Telephone: (301) 496-9531

Direct inquiries regarding fiscal matters to:

Ms. Sara Stone
Grants Management Coordinator
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Suite 242
6120 Executive Boulevard
Rockville, MD 20852
Telephone: (301) 496-7227, Extension 66
Facsimile: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.395, Cancer Treatment Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A. (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285), and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

PREPARATION FOR AIDS/HIV VACCINE EVALUATIONS

NIH GUIDE, Vol. 21, No. 8, February 28, 1992

RFA AVAILABLE: AI-92-05

P.T. 34; K.W. 0715008, 0740075, 1002019

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: March 30, 1992
Application Receipt Date: May 13, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The purpose of this RFA is to support developmental projects designed to establish collaborative studies, involving U.S. and foreign institutions, that (1) provide baseline data for determining the feasibility of

conducting AIDS/HIV vaccine trials in international settings and (2) prepare international sites to conduct HIV vaccine efficacy trials. The National Institute of Allergy and Infectious Diseases (NIAID) anticipates initiating clinical trials of AIDS/HIV vaccines as early as December 1993 at domestic sites and shortly thereafter at international locations.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Preparation for AIDS/HIV Vaccine Evaluations, is related to the priority area of HIV infections. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-0473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. All applicants must demonstrate the existence of a collaborative relationship with a foreign institution and the potential for productivity in the area of epidemiologic research related to HIV/AIDS vaccine testing. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Successful applicants funded under this RFA will be supported through NIH Exploratory/Developmental Grants (R21). The R21 grant mechanism is used for this initiative to develop the capability to conduct HIV/AIDS vaccine clinical trials in international settings. The total project period may not exceed two years.

FUNDS AVAILABLE

The NIAID has set aside \$3,000,000 for funding the total costs for the initial year of this RFA. The total first-year cost of individual applications, including direct and indirect costs, may not exceed \$600,000 per year. It is anticipated that five to six awards shall be made for the first year dependent upon receipt of a sufficient number of applications of high scientific merit. Awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

This RFA seeks to fund developmental projects designed to establish collaborative research studies, involving U.S. and foreign institutions, that (1) provide baseline data for determining the feasibility of conducting AIDS/HIV vaccine trials in international settings and (2) prepare international research sites to conduct HIV vaccine efficacy trials. The specific objectives of this RFA are to:

- o define the incidence of HIV infection in population groups at high risk of acquiring HIV infection;
- o identify selected biological and behavioral co-factors of adult and/or perinatal transmission of HIV;
- o collaborate in research that studies the distribution of genetic and antigenic variants of HIV in different population groups; and
- o strengthen the infrastructure and field management capacity needed to undertake potential future HIV vaccine efficacy trials.

SPECIAL REQUIREMENTS

All applicants responding to this RFA MUST satisfactorily address the following issues:

1. Applicants must demonstrate the extent to which a potentially productive institutional relationship has been established between the U.S. and foreign institutions that will be responsible for the Preparation for AIDS/HIV Vaccine Evaluations (PAVE) project.
2. Since most of the research will be conducted in a foreign country, funds must be allocated accordingly. The NIAID has determined that at least 70 percent of all direct costs must be spent in the foreign country.
3. Applicants must assure that research participants will be provided treatment for sexually transmitted diseases (STDs), consistent with the standards of care for the country in which the PAVE is located if the participants are diagnosed with an STD in any component of the PAVE.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR THE INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are encouraged to submit a letter of intent, by March 30, 1992, that includes: a brief

description of the study population and the thrust of research activities; the names of the principal and other key investigators, if known; the identity of the U.S. and foreign institutions involved in the collaboration; and the number and title of this RFA.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIAID staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to Dr. Robert D. Fischer at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for this grant. These forms are available at most U.S. institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda MD 20892, telephone 301-496-7441; and from the NIH program administrator named below.

Applications must be received by May 13, 1992.

REVIEW CONSIDERATIONS

Review criteria will be those used for review of multicomponent, inter-related project applications. Additional review criteria are outlined in the RFA. Applications may be triaged by an NIAID peer review group on the basis of relative competitiveness. Applications deemed to have significant and substantial merit will be reviewed by a review committee convened by the Scientific Review Branch, Division of Extramural Activities, NIAID. The second level of review will be provided by the National Advisory Allergy and Infectious Diseases Council.

AWARD CRITERIA

The anticipated date of award is September 30, 1992.

INQUIRIES

Direct requests for the RFA and inquiries regarding programmatic issues to:

Robert D. Fischer, M.D., M.P.H.
Epidemiology Branch, DAIDS
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard, Solar Building
Bethesda, MD 20892
Telephone: (301) 496-6177
FAX: (301) 402-1506

For overnight and courier service, USE "Rockville, MD 20852" in place of "Bethesda, MD 20892"

Direct inquiries regarding fiscal matters to:

Jane Unsworth
Chief, DAIDS Section
Grants Management Branch
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard, Solar Building
Bethesda, MD 20892
Telephone: (301) 496-7075

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.856, Microbiology and Infectious Disease Research, and No. 93.855, Immunology, Allergic and Immunologic Diseases Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulation 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Authority for the international aspects of this program are provided by Public Law 86-610, the "International Health Research Act of 1960" and Public Law 100-607, the "Health Omnibus Program Extension Act of 1988."

CLINICAL TRIALS FOR DIGESTIVE AND NUTRITIONAL DISEASES

NIH GUIDE, Volume 21, Number 8, February 28, 1992

RFA AVAILABLE: DK-92-15

P.T. 34; K.W. 0755015, 0715085, 0765033, 0715145

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: May 15, 1992
Application Receipt Date: July 15, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION

PURPOSE

The Division of Digestive Diseases and Nutrition of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites applications for single and multicenter clinical trials in digestive and nutritional diseases. This RFA is a follow-up to an RFA (DK-91-02) entitled "Planning Grants for Clinical Trials in Digestive and Nutritional Diseases," NIH Guide for Grants and Contracts, Vol. 19, No. 39, November 2, 1990. Responses, however, are not limited to recipients of that solicitation.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Clinical Trials for Digestive and Nutritional Diseases, is related to the priority area of diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, public and private, non-profit and for-profit organizations such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

Support of this program will be through the NIH research project grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Except as otherwise stated in this announcement, awards will be administered under the PHS grants policy as stated in the PHS Grants Policy Statement. The total requested project period for applications submitted in response to this RFA may not exceed five years. The earliest possible award date will be April 1, 1993.

FUNDS AVAILABLE

For FY 1993, \$1.2 million in total costs (direct plus indirect) will be committed to fund applications submitted in response to this RFA. It is anticipated that up to two awards will be made. However, this funding level is dependent upon the receipt of a sufficient number of applications of high scientific merit and availability of funds. In order to help meet NIDDK goals for managing the costs of biomedical research, applicants must limit the requests to not more than \$400,000 direct costs for the initial budget period.

RESEARCH OBJECTIVES

Recent advances in basic biomedical research have provided new insights into the pathogenesis of many nutritional and digestive diseases. These advances have led to new possibilities for therapeutic intervention in these diseases. New therapies and interventions are best evaluated in prospective, randomized, controlled clinical trials.

In the area of digestive diseases and nutrition there are several diseases and conditions that warrant studies of new therapeutic interventions. Digestive and nutritional diseases and conditions for which no satisfactory long-term therapies exist include helicobacter pylori infection, inflammatory bowel disease, primary biliary cirrhosis, and primary sclerosing cholangitis. Other areas of importance are innovative approaches to prevention, management, and treatment of portal hypertension, recurrent liver disease after hepatic transplantation, and adolescent and adult obesity. These conditions are significant in that they affect many Americans and cause considerable morbidity and mortality.

SPECIAL REQUIREMENTS

Plans to submit quarterly progress reports to the NIH including recruitment data, indices of quality control, mortality, morbidity, and changes in the protocol should be included. Applicants are advised to include such plans in their budget requests and a statement about willingness to participate in coordination among investigators.

STUDY POPULATIONS

It is NIH policy that women and minorities must be included in clinical study populations unless there is a good reason to exclude them. The study design must seek to identify any pertinent gender or minority population differences. If the required information is not contained within the application, the application will be returned without review.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 15, 1992, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. The letter of intent is to be sent to:

Chief, Review Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 605
Bethesda, MD 20892
Telephone: (301) 496-7083

APPLICATION PROCEDURES

The research grant application form PHS-398 (revised 9/91) is to be used in applying for these grants. The form is available from most institutional business offices or from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, Maryland 20892. The RFA label available in the 9/91 revision of PHS 398 application form must be affixed to the bottom of the face page.

REVIEW CONSIDERATIONS

Those applications which are complete and responsive will be evaluated for scientific/technical merit by an appropriate peer review group convened by the NIDDK. Following this initial review, the applications will be given a secondary review by the NIDDK Advisory Council unless not recommended for further consideration by the IRG.

Administrative guidelines which include specific review criteria for clinical trials are available and should be requested from the Clinical Trials Program Director listed under Inquiries.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged.

It is imperative that prospective applicants obtain copies of the RFA and "Administrative Clinical Trial Guidelines" before developing their applications. Requests for these documents should be directed to:

Tommie Sue Tralka
Director, Clinical Trials Program
Division of Digestive Diseases and Nutrition
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A15
Bethesda, MD 20892
Telephone: (301) 496-9717

Direct inquiries regarding fiscal matters to:

Ms. Thelma Jones
Grants Management Specialist
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 630
Bethesda, MD 20892
Telephone: (301) 496-7467

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93-848. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99- 158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

DEPRESSION IN LATE LIFE

NIH GUIDE, Volume 21, Number 8, February 28, 1992

PA NUMBER: PA-92-44

P.T. 34; K.W. 0715072, 0710010, 0755030, 0785055, 0414014

National Institute of Mental Health

PURPOSE

The purpose of this program announcement (PA) is to stimulate the development of new research related to the diagnosis and treatment of depression in late life. At the National Institutes of Health (NIH) Consensus Development Conference on the Diagnosis and Treatment of Depression in Late Life, held November 4-6, 1991, progress in the development of the scientific knowledge base was reviewed. Significant attention was paid to the epidemiology, pathogenesis, pathophysiology, and treatment of depression in geriatric patients and to issues of prevention and symptomatic management. In addition, the Consensus Panel identified a number of research issues as deserving special attention at this time (see Research Objectives, below). These issues, and others of significant programmatic interest to the National Institute of Mental Health (NIMH), represent the major

focus of this program announcement.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Depression in Late Life, is related to the priority areas of mental health and mental disorders, and older adults. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone: 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by any public and private, non-profit and for-profit organization such as a university, college, hospital, laboratory, units of State or local governments, and eligible agencies of the Federal Government. Women and minorities are encouraged to apply.

MECHANISMS OF SUPPORT

In addition to the traditional research project grant (R01), other mechanisms that are available include the First Independent Research Support and Transition (FIRST) Award (R29) and the small grant (R03). Specialized announcements are available from Anne Cooley, Room 9-97, 5600 Fishers Lane, Rockville, Maryland 20857, telephone: 301-443-4673.

Terms and Conditions of Support

Grant funds may be used for expenses clearly related and necessary to conduct the proposed project, including both direct costs and allowable indirect costs. Applicants must show any special administrative or programmatic limitations on the types of activities for which funds may be used, e.g., maximum total award each year, maximum for particular types of costs such as stipends or requirements to attend periodic meetings of grantees. In general, funds may not be used to establish or operate a treatment, rehabilitation, or other service program.

Grants must be administered in accordance with the PHS Grants Policy Statement (revised October 1, 1990).

Federal regulations at 42 CFR Part 52, "Grants for Research Projects," and Title 45 CFR Parts 74 and 92, generic requirements concerning the administration of grants, are applicable to this award.

Period of Support

Support for regular research grants may be requested for a period of up to five years (renewable for subsequent periods). Annual awards will be made subject to continued availability of funds and progress achieved. A competing supplemental application may be submitted during an approved period of support to expand the scope or protocol of a project during the approved period. A competing continuation (i.e., renewal) application may be submitted before the end of an approved period of support to continue a project.

Availability of Funds

In fiscal year 1993, the NIMH estimates that approximately \$7,000,000 will be available to support 10-12 new and 25 continuation grants under this announcement. The expected average amount of an award is approximately \$180,000. However, the amount of funding available will depend on appropriated funds and program priorities at the time of award.

RESEARCH OBJECTIVES

Background

Depressive illness is a major public health problem among the elderly. Late-onset disease, that is, depression with first onset at age 65 or over, as well as recurrent episodes of adult onset depression in geriatric patients, constitute significant sources of heterogeneity in this growing segment of the population. With increasing longevity and the aging of the "baby boom" generation, the number of people 65 years and older will increase by 40 percent between 1984 and 2010 and will represent nearly 14 percent of the general U. S. population. Elderly patients with depression are already overrepresented in hospitals, outpatient clinics, and institutions. The 1985 National Nursing Home Survey found that 25 percent of nursing home residents had major depression, not including the 63 percent who were cognitively impaired.

There is substantial evidence that the prognosis of depression in the elderly and treatment response may be poorer than in younger patients. Although pharmacotherapy is effective in older patients, it may not be as effective as it is in younger adults, with less than a 50-percent response rate. Evidence for the efficacy of psychotherapy in older depressed adults has emerged only recently. Reasons for these differences remain to be explicated but include the possibilities that depression in late life is different in phenomenology and natural history; that structural and metabolic derangements, concurrent medical illness, or personality may complicate the clinical course and response to treatment; that the physiological effects of aging per se may increase sensitivity to toxic effects or decrease sensitivity to therapeutic effects of medication; or that significant age-related pharmacokinetic and pharmacodynamic effects may impair response. The increased prevalence of suicide in older white males, issues of bereavement-related depression, and depression among residents of long-term care facilities represent significant concerns.

Research addressing issues of depression in late life was the subject of the November NIH Consensus Development Conference. Interested individuals may obtain a copy of the Panel Report of the Consensus Development Conference on the Diagnosis and Treatment of Depression in Late Life through the Office of Medical Applications

of Research, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892 (Telephone 301/496-1144). This PA derives directly from the recommendations for future research identified by this conference.

Research Goals and Scope

NIMH encourages applicants to study the broad range of issues related to depression in late life. These include: epidemiology; clinical, etiological, and biological heterogeneity including subsyndromal and delusional forms; course and outcome; comorbidity; quality of life; cohort effects; biological, personality, and psychosocial correlates; brain structural and functional correlates; pharmacologic and other biological treatments, psychotherapeutic, and combined approaches to acute, continuation, and maintenance treatment; treatment non-response; pharmacokinetics, toxicity, and compliance in treatment; protective/innoculating factors; prevention of recurrence and of initial episodes; availability and effectiveness of services; and considerations relating to suicide, bereavement, and residential care facilities and settings.

The Consensus Panel identified the following research issues as deserving special attention at this time:

Improvement of the diagnosis and identification of elderly persons most likely to benefit from treatment

Clarification of the relationship between subcortical brain abnormalities, depressive and cognitive symptomatology, and early- versus late-onset depression in the elderly

Studies of the pharmacokinetic differences in the very old and in ethnic minorities, with special attention to the prognostic value of metabolic subtyping

Research on the relationships between depression and physical illness, including how psychological factors can exacerbate physical conditions

Initiation of prospective longitudinal and cross-sequential studies to identify general risk factors (including contextual and event-related life stress) and those specific deficits in the elderly (e.g., sensory loss) and describe the course of depression

Exploration of the basis for differential occurrence of depression and suicide rates in demographic subgroups

Determination of approaches to long-term treatment, with particular attention to the efficacy of electroconvulsive therapy (ECT) as a continuation and maintenance treatment in late-life depression

Study of the treatment of pathological grief, including assessment of the efficacy of psychological and pharmacological treatments, and when in the course of grief they should be used

Conduct of clinical trials and observational studies of treatment in the very old, the elderly in minority and underserved communities and in institutional settings, and the elderly with medical illness

Development and evaluation of psychosocial treatments, including marital or family therapy that are specifically linked to the needs of the elderly; determination of how psychosocial and biological treatments may complement or provide alternatives to each other

Evaluation of demonstration projects focused on innovative models of care delivery, particularly those that emphasize coordinated services and outreach efforts to depressed elderly people

Development of long-term clinical trials with broad-based assessment of outcome (including economic and social impact) to determine the extent to which effective recognition and treatment benefit patients, their families, and society.

The NIMH encourages creative collaboration between research centers, particularly academic sites, and the public centers where many severely ill patients receive care. The advances made at academic research centers are slow to make their way to the public centers because of the lack of collaboration between the sites. Through the general impact of introducing scientific expertise and interests and through targeted research studies, stronger research/public partnerships could promote significant improvements in clinical care.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources or a Mental Health Clinical Research Center (MHCRC) may wish to identify the GCRC or MHCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from either the GCRC or MHCRC program director or principal investigator could be included with the application.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

Applications/proposals for ADAMHA grants and cooperative agreements are required to include both women and minorities in study populations for clinical research, unless compelling scientific or other justification for not including either women or minorities is provided. This requirement is intended to ensure that research findings will be of benefit to all persons at risk for the disease, disorder, or condition under study. For the purpose of these policies, clinical research involves human studies of etiology, treatment, diagnosis, prevention, or epidemiology of diseases, disorders or conditions, including but not limited to clinical trials; and minorities include U.S. racial/ethnic minority populations (specifically: American Indians or Alaskan Natives, Asian/Pacific Islanders/Blacks, and Hispanics).

ADAMHA recognizes that it may not be feasible or appropriate in all clinical research projects to include

representation of all the full array of U.S. racial/ethnic minority populations. However, all researchers are urged to assess carefully the feasibility of including the broadest possible representation of minority groups.

Applications should include a description of the composition of the proposed study population by gender and racial/ethnic group, and the rationale for the number and kinds of people selected to participate. This information should be included in the form PHS 398 in Section 2, A-D, of the Research Plan and summarized in Section 2, E, Human Subjects.

Applications should include in their study design gender and/or minority representation appropriate to the scientific objectives of the work proposed. If representation of women or minorities in sufficient numbers to permit assessment of differential effects is not feasible or is not appropriate, the reasons for this must be explained and justified. The rationale may relate to the purpose of the research, the health of the subjects, or other compelling circumstances (e.g., if in the only study population available there is a disproportionate representation in terms of age distribution, risk factors, incidence/prevalence, etc., of one gender or minority/majority group).

If the required information is not contained within the application, the application will be returned. Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If gender and/or minority representation/justification are judged to be inadequate, reviewers will consider this as a deficiency in assigning the application a priority score.

All applications/proposals for clinical research submitted to ADAMHA are required to address these policies. ADAMHA funding components will not award grants that do not comply with these policies.

Protection of Human Subjects

The Department of Health and Human Services has regulations for the protection of human subjects and has developed additional regulations for the protection of children. A copy of these regulations (45 CFR 46, Protection of Human Subjects) and those pertaining specifically to children are available from the Office of Protection from Research Risks, National Institutes of Health, Bethesda, Maryland 20892, telephone (301) 496-7041. Specific questions concerning protection of human subjects in research may be directed to NIMH staff members listed under Further Information.

APPLICATION PROCEDURES

Applicants are to use the grant application form PHS 398 (rev. 9/91). The number and title of this PA-92-44 must be typed in item number 2 on the face page of the PHS application form.

Applications kits containing the necessary forms and instructions may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following office may be contacted for the necessary application materials:

Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-05
Rockville, MD 20857
Telephone: (301) 443-4414

The signed original and five legible copies of the completed application should be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will be reviewed for scientific and technical merit by an initial review group (IRG) composed of primarily non-federal scientific experts. Final review is by the appropriate national advisory council. Summary statements of IRG discussions are sent to applicants as soon as possible following IRG review.

Review Criteria

- o Significance of research objectives to public health goals of the announcement
- o Adequacy of theoretical framework of the proposed research and appropriateness of research methods
- o Scientific merit of the design
- o Adequacy of facilities and core resources
- o Adequate representation of women and minorities
- o Adequacy of proposed procedures for protecting human and animal subjects
- o Appropriateness of the budget

Receipt and Review Schedule

Applications will be accepted in accordance with the usual receipt dates for applications:

Receipt of Applications	Initial Review	Advisory Council Review	Earliest Award Date
Feb 1/Mar 1*	June	Sep/Oct	Dec 1
Jun 1/Jul 1*	Feb	Oct/Nov	Apr 1
Oct 1/Nov 1*	May	Feb/Mar	Jul 1

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* Amended applications and competing continuation the exception of center applications. All center applications are to be submitted on the earlier dates.

Applications arriving after the above receipt dates are subject to assignment to the next review cycle or may be returned to the applicant without review if requested by the applicant.

AWARD CRITERIA

Applications recommended for approval by the appropriate National Advisory Council will be considered for funding on the basis of overall scientific and technical merit of the research as determined by peer review, program needs and balance, and availability of funds.

INQUIRIES

Applicants are encouraged to discuss their planned research with NIMH staff before submitting a formal grant application. Further information may be obtained from:

Barry D. Lebowitz, Ph.D.
 Chief, Mental Disorders of the Aging Research Branch
 Division of Clinical Research
 National Institute of Mental Health
 Parklawn Building, Room 7-103
 5600 Fishers Lane
 Rockville, MD 20857
 Telephone: (301) 443-1185

For further information on grants management issues, applicants may contact:

Stephen J. Hudak
 Chief, Grants Management Section
 National Institute of Mental Health
 Parklawn Building, Room 7C-23
 5600 Fishers Lane
 Rockville, MD 20857
 Telephone: (301) 443-4456

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.242. Applications will be accepted under the authority of Section 301 of the Public Health Service Act, P.L. 78-410, as amended, 72 U.S.C. 241, and subject to availability of funds. This announcement is not subject to the intergovernmental review requirements of Executive Order 12372, as implemented through DHHS regulations at 45 CFR Part 100.

ERRATUM

MULTICENTER STUDIES OF DIET AND LIPOPROTEINS IN HUMANS

NIH GUIDE, Vol. 21, No. 8, February 28, 1992

RFA: HL-92-03-H

P.T. 34; K.W. 0710095, 0755015, 0715040, 0755018, 0765020, 0710030

National Heart, Lung, and Blood Institute

Application Receipt Date: April 23, 1992

The RFA, "Multicenter Studies of Diet and Lipoproteins in Humans," was published in the NIH Guide for Grants and Contracts, Vol. 20, No. 47, December 20, 1991. Investigators submitting applications for both a clinical center and a field center must submit separate applications for each. Each application must be self-contained, and must indicate the Principal and Co-Investigators, must include its own budget and all appropriate assurances, and indicate clearly whether the application is for a Field Center or a Coordinating Center.

For further information, contact:

Abby G. Ershow, Sc.D.
 Project Scientist, Lipid Metabolism-Atherogenesis Branch
 National Heart, Lung, and Blood Institute
 Federal Building, Room 401
 7550 Wisconsin Avenue
 Bethesda, MD 20892
 Telephone: (301) 496-1681
 FAX: (301) 496-9882

NIH GUIDE

For Grants and Contracts

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Bethesda, Maryland 20892

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21, No. 9, Part I of II
March 6, 1992

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NATIONAL WORKSHOPS ON THE PROTECTION OF HUMAN SUBJECTS

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P.T. 42; K.W. 0783005

National Institutes of Health

Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are sponsoring a series of workshops on the responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

SOUTH MIDWESTERN WORKSHOP

DATES: February 20 and 21, 1992

WORKSHOP SITE: San Antonio, TX

SPONSORS: University of Texas Health Science Center at San Antonio

7703 Floyd Curl Drive

San Antonio, TX 78284-7972

St. Mary's University

One Camino Santa Maria

San Antonio, TX 78228-8572

REGISTRATION CONTACT:

Ms. Angie Khan

Institutional Coordinator of Research Review

University of Texas Health Science Center at San Antonio

7703 Floyd Curl Drive (Room 402L)

San Antonio, TX 78284-7972

Telephone: (512) 567-2351

TOPIC: Identifying and Assessing Risks in Human Subject Research

SOUTHWEST WORKSHOP

DATES: March 24, 25, and 26, 1992

WORKSHOP SITE: Sheraton Old Town Hotel

800 Rio Grande Blvd., N.W.

Albuquerque, NM 87104

SPONSORS:

University of New Mexico

Albuquerque, NM 87131-5126

Navajo Community College

Shiprock, NM 87420

REGISTRATION CONTACT:

University of New Mexico

Office of Continuing Medical Education

Health Sciences and Services Building (Room 140)

Box 713

Albuquerque, NM 87131-5126

Telephone: (505) 277-3942

TOPIC: Ethics, Justice, and Tribal Participation in Research with American Indians

NOTE: In conjunction with this Workshop, a session entitled, "Basic Training for IRB Members," will be held from 1:00 p.m. on March 24 until noon on March 25. During this session the Workshop participants will be divided into four IRBs that will review four different research protocols involving American Indians. The full conference will convene at 1:00 p.m. on March 25 and continue until 6:00 p.m. on March 26.

NORTHEASTERN WORKSHOP

DATES: April 27 and 28, 1992

WORKSHOP SITE: Philadelphia, PA

SPONSORS:

University of Pennsylvania
133 South 36th Street, Suite 300
Philadelphia, PA 19104-3246

Lincoln University
Lincoln University, PA 19352

REGISTRATION CONTACT:

Ms. Lynn Bevan
Assistant Director
Office of Research Administration
University of Pennsylvania
133 South 36th Street, Suite 300
Philadelphia, PA 19104-3246
Telephone: (215) 898-2614

TOPIC: The Shifting Ground: Current Issues for the Protection of Human Subjects on Biomedical and Behavioral Research

For further information regarding these workshops and future NIH/FDA National Protection of Human Subjects Workshops, please contact:

Ms. Darlene Marie Ross
Executive Assistant for Education
Division of Human Subject Protections
Office for Protection from Research Risks
9000 Rockville Pike
Building 31, Room 5B59
Bethesda, MD 20892
Telephone: (301) 496-8101

NOTICES OF AVAILABILITY (RFPs AND RFAs)

INITIATIVES FOR MINORITY STUDENTS: BRIDGES TO THE FUTURE

NIH GUIDE, Volume 21, Number 9, March 6, 1992

RFA: GM-92-02

P.T. 44, FF; K.W. 0502000, 0720005

National Institute of General Medical Sciences

Letter of Intent Receipt Date: April 1, 1992

Application Receipt Date: May 12, 1992

PURPOSE

The National Institute of General Medical Sciences (NIGMS) and the Office of Minority Programs (OMP), National Institutes of Health (NIH), solicit applications for two new initiatives aimed at increasing the number of underrepresented minorities entering careers in biomedical research. The programs target two different underrepresented minority student populations, those in terminal Master of Science (M.S.) degree programs and those in two-year junior or community colleges, since these have been identified as two key transition points for students considering research careers. These initiatives seek to broaden and expand existing programs and to encourage the development of new and innovative approaches to improve the academic competitiveness of underrepresented minority students graduating from these programs, thereby facilitating their transition into the next stage towards careers in biomedical research.

For purposes of this announcement, underrepresented minority students are individuals belonging to a particular ethnic or racial group that has been determined by the grantee institution to be underrepresented in biomedical or behavioral research. Nationally, individuals who have been found to be underrepresented in biomedical or behavioral research include, but are not limited to, Black Americans, Hispanic Americans, Native Americans and Pacific Islanders.

MECHANISM OF SUPPORT

Awards under this RFA will use the institutional education project (R25) grant. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed two years.

This RFA is a one-time solicitation. Future unsolicited competing applications will not be accepted.

Institutions may apply for either or both programs; however, separate applications for each program are required. The program must be identified clearly on the face page of the application in item 1.

FUNDS AVAILABLE

The Fiscal Year 1992 appropriation provides \$2,000,000 for these initiatives. NIH staff anticipate making six to ten 2-year awards using multi-year funding. Requested direct costs are not to exceed \$300,000 for the two-year period. Indirect costs will be paid at 8 percent of the direct costs minus appropriate exclusions.

OBJECTIVES

Program #1: Transition From Master's Degree to Ph.D. Programs

This program seeks to promote the expansion and enhancement of existing transitional activities between those institutions that offer the M.S. degree as the terminal academic degree in the sciences and that have significant enrollments of underrepresented minority students and research universities with doctoral-degree (Ph.D.) programs. The objective is to facilitate the transition of minority students into science Ph.D. programs when they complete the M.S. degrees. Students receiving the M.S. degree in one field of science may pursue the Ph.D. in a different field if the Ph.D. is in an area of science related to biomedical research.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, private and public, institutions that have existing educational programs aimed at helping students move from M.S. programs into Ph.D. programs. The existing programs need not have been developed specifically to target underrepresented minority graduates or science majors. State and local systems of higher education with existing transitional programs may also be eligible to apply. However, applicants from such organizations should talk with the Grants Management Officer identified at the end of this announcement about special issues concerning PHS grants to governments.

A program must include a partnership between at least two institutions: one that offers the M.S. degree as the terminal degree in the sciences and that has a significant enrollment of underrepresented minorities, and one research university providing Ph.D. degree programs in areas relevant to the biomedical sciences. However, the application may involve a consortium of several colleges and universities, and may include several institutions within a single state system. One participating institution or a single system of higher education must be designated as the grantee institution and must submit the application. Proposals must include subcontracts or formal collaborative agreements with all other participating institutions.

An institution offering both the M.S. and the Ph.D. degrees may not use funds from this program for graduates of its own M.S. degree programs to enter its own Ph.D. programs, even if the student is changing fields or moving from one department, school, or college to another. The program seeks to promote and enhance partnerships BETWEEN institutions.

SPECIAL REQUIREMENTS

Collaborative agreements should take the form that best fits the needs and situations of the institutions involved. The challenge for the project director, with the help of the other participants, is to design an expanded and enhanced partnership that will focus attention and adequate resources to the M.S. institutions to enhance the academic competitiveness of their M.S. graduates.

The applicant must describe the existing transition program and explain how it would be altered to meet the needs of this initiative. The nature and extent of underrepresented minority student participation must be thoroughly delineated. The applicant should also describe the M.S. institution's success in training M.S. students in the sciences, including information on the numbers of minority students receiving the M.S. and data on subsequent careers or education of their graduates.

Institutions with NIH National Research Service Award (NRSA) institutional training grants and/or Minority Biomedical Research Support (MBRS) Grants must define the relationship between those programs and this transition program. They must delineate how this initiative will influence their partnerships with the other participants and the manner in which underrepresented minority graduate students will interact with the NRSA and/or MBRS program(s).

In addition, modifications to existing "bridge" programs must be described with special attention to the needs and special requirements of the underrepresented minority student body. They may include, but are not limited to, the following elements:

- o providing research opportunities for M.S. students at the Ph.D. institution or in private industrial laboratories; students may receive compensation for these activities;
- o establishing a mentoring program for M.S. students with faculty at the Ph.D. institution;

- o strengthening the research capability of the M.S.-granting college (e.g., by faculty research collaborations, joint seminar programs);
- o enhancing the curriculum of the M.S. institution (e.g., special courses, seminars);
- o students from either institution taking classes at the other institution;
- o guaranteeing acceptance into the participating Ph.D. program(s) for students completing the M.S. program;
- o academic counseling for M.S. students, with a particular focus on encouraging students to pursue research careers in the biomedical sciences.

It is an expectation of NIGMS and OMP that students who enter Ph.D. programs as a result of this enhancement program will receive support, if needed, while progressing satisfactorily in Ph.D. research training programs. Applicants should describe the type(s) of support that would be available to such students.

Additional requirements are detailed below.

Program #2: Transition From Two-year Colleges to Institutions Awarding the Baccalaureate Degree

This program is designed to refine and extend existing "bridge" programs that facilitate the transfer of students at two-year colleges with significant enrollments of underrepresented minority students into colleges with baccalaureate degree programs in the sciences. The goal is to increase the number of underrepresented minority students who graduate with Bachelor of Science (or equivalent) degrees in the sciences related to biomedicine.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, private and public, institutions with existing educational programs aimed at helping students move from two-year colleges into B.S. degree programs, although the existing programs need not specifically target underrepresented minorities or science majors. State and local systems of higher education with existing transitional programs may also be eligible to apply. However, applicants from such organizations should talk with the Grants Management Officer identified at the end of this announcement about special issues concerning PHS grants to governments.

Programs must include at least two institutions: one college or university offering the B.S. degree (or equivalent) in areas of science relevant to biomedical research, and one two-year institution with a significant enrollment of underrepresented minority students. However, the program may include a consortium of several two-year and baccalaureate institutions, and may include several institutions within a single state system. One baccalaureate-granting institution or a single system of higher education must be designated as the grantee institution and must submit the application. Proposals must include formal collaborative agreements or subcontracts with all other participating institutions.

SPECIAL REQUIREMENTS

Collaborative agreements should foster partnerships that best fit the needs and situations of the institutions involved. The challenge for the program director, with the help of the other participants, is to design a program that focuses attention and adequate resources to help the two-year institution enhance the academic competitiveness of its graduates.

The application must include a description of the existing transition program and describe how the program will be modified to accommodate the goals of this initiative. The nature and extent of underrepresented minority student participation must be thoroughly delineated. Colleges with NIH funding through the Minority Biomedical Research Support (MBRS) and/or the Minority Access to Research Career (MARC) programs must define the relationship between those programs and this transition program. They must delineate how this enhancement program will influence their partnerships with the other participants and the manner in which underrepresented minority students in the transition program will interact with the MBRS and/or MARC programs.

In addition, these existing "bridge" programs must be modified as needed to meet the special requirements of underrepresented minority students interested in science. They may include, but are not limited to, the following elements:

- o providing laboratory research experiences at the baccalaureate institution for students enrolled in the two-year institution; students may receive compensation for these activities;
- o establishing a mentoring program with faculty at the baccalaureate institution;
- o providing research opportunities at the baccalaureate institution for faculty of the two-year college;
- o enriching the curriculum at the two-year institution (e.g., special science courses);
- o enabling students from the two-year institution to take courses and/or participate in seminar programs at the baccalaureate college;
- o developing visiting lectureships at the two-year college by science faculty from the baccalaureate institution;
- o developing courses at the two-year college jointly taught by faculty of both institutions;

- o guaranteeing acceptance as juniors into the participating baccalaureate program(s) for students who participated successfully in the enhancement program;
- o academic counseling (e.g., guidance in course selection, tracking and providing assistance to students who express and interest or show special aptitude for science);
- o additional enrichment activities, such as tutoring, to enhance the student's transition to the baccalaureate college;
- o other innovative plans to coordinate these programs.

Additional requirements are detailed below.

GENERAL REQUIREMENTS FOR BOTH PROGRAMS

Allowable Costs

If appropriate, the budget request may be divided into two phases: a planning phase with its attendant budget for the enhancement, expansion, and modification of the existing partnership program; and an implementation phase with its attendant budget. The planning phase costs should be minimal and may include such items as compensation for release time for faculty and administrators for each of the participating institutions and travel between the participating institutions. This phase of the project should not exceed a period of one year. The implementation phase may include the costs of administering and coordinating the partnership programs within and between each of the participants. Compensation for student participation in research experiences may take the form of salaries, fringe benefits and/or tuition waivers for students and salary compensation for release time for faculty participating in research projects. Costs related to curriculum enhancement may also be requested.

Reporting Requirements

A progress report will be required at the end of the planning phase (if any) or at the end of the first year, whichever is shorter. A final report will be required 90 days after the termination date of the award and must include a Statement of Appointment Form (form 2271) for each student participant and a report of the educational benefits to each student of the partnership program.

During the planning phase or first year of the award, program directors should develop plans for following the subsequent careers and educational achievements of the participating students, which will be used as part of the evaluation of the effectiveness of these initiatives. The progress report should include a description of these plans.

During or after the project period, program directors will be asked to share information and experiences and help evaluate the effectiveness of the programs. OMP and/or NIGMS may convene a meeting of program directors to discuss these programs.

LETTER OF INTENT

Prospective applicants are requested to submit by April 1, 1992, a letter of intent that includes a descriptive title of the proposed plan, the name, address, and telephone number of the program director, the identities of other key personnel and participating institutions, and the number and title of the RFA. Applicants should indicate the specific program(s) (Program 1: M.S. to Ph.D. Transition or Program 2: Two-year to Four-year Transition) to which they intend to apply. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIH staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Americo Rivera, Jr., Ph.D.
National Institute of General Medical Sciences
Westwood Building, Room 909
Bethesda, MD 20892
Telephone: (301) 496-7001
FAX: (301) 402-0019

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, NIH, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 496-7441; and from the NIGMS program administrator named below.

The RFA label in the PHS 398 application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA number and title must be typed on line 2A of the face page form, the "YES" box must be marked, and "R25" typed in 2B.

Submit a signed, typewritten original of the application, including the Checklist, and three photocopies of the signed application in one package to:

DIVISION OF RESEARCH GRANTS
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to Dr. Americo Rivera, Jr. at the address given below.

Applications must be received by May 12, 1992. Applications arriving after that date will be returned to the applicant.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH program staff. Incomplete and/or unresponsive applications will be returned to the applicant without further consideration. Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific and technical merit by appropriate peer review groups in the Division of Research Grants (DRG). The second level of review will be provided by the National Advisory General Medical Sciences Council.

Review criteria:

- o qualifications and experience of the Principal Investigator and staff to carry out the proposed program;
- o appropriateness of the existing transition program and of the plans to modify or expand this program to meet the goals of the solicitation;
- o availability of significant numbers of underrepresented minority students in the participating science department(s) who are interested in studying further in biomedical and health-related fields;
- o evidence of underrepresented minority students progressing to higher education in the sciences;
- o budget and cost-effectiveness of the project including appropriateness to the scope of the program, benefit to the students, number of students involved, and responsible and prudent senior personnel costs;
- o evidence of institutional commitment, for each institution, and strength of the collaborative efforts between institutions to foster professional development of underrepresented minority faculty and to train underrepresented minority students in the biomedical sciences;
- o appropriateness of the administrative plan for managing the proposed program, including adequacy of space and other institutional resources;

AWARD CRITERIA

The anticipated date of award is September 30, 1992. Award decisions will be based on the technical merit of the applications based on the review criteria, the geographical distribution of the awardee institutions, and diversity of underrepresented minority student participants. Awards can be made only to institutions with financial management systems and management capabilities that are acceptable under PHS policy. Awards will be administered under the PHS Grants Policy Statement.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to the program administrator:

Americo Rivera, Jr., Ph.D.
National Institute of General Medical Sciences
Westwood Building, Room 909
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7001

Direct inquiries regarding fiscal matters to:

Ms. Carol Tippery
Grants Management Officer
National Institute of General Medical Sciences
Westwood Building, Room 953
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7746

AUTHORITY AND REGULATIONS

Awards are authorized under the Public Health Service Act, Title IV, Part A, (Sections 301 and 405, as amended, 42 USC 241 and 284) and administered under PHS grants policies and Federal Regulations 42 CFR 52, 45 CFR Part 74 and 45 CFR Part 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21, No. 9, Part II of II
March 6, 1992

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NOTICES OF AVAILABILITY (RFPs AND RFAs)

NATIONAL TEMPORAL BONE, HEARING, AND BALANCE PATHOLOGY RESOURCE REGISTRY

NIH GUIDE, Volume 21, Number 9, March 6, 1992

RFP AVAILABLE: NIH-DC-92-07

P.T. 34; K.W. 0780000, 0780030, 0775005

National Institute on Deafness and Other Communication Disorders

The National Institute on Deafness and Other Communication Disorders, National Institutes of Health, has a requirement to establish the National Human Temporal Bone, Hearing and Balance Pathology Resource Registry that will serve as a National registry or clearinghouse, maintaining a catalog of currently active and inactive temporal bone collections. In addition, the Registry will encourage the pursuit of human temporal bone research by: disseminating pertinent information, developing and fostering temporal bone professional education activities, and encouraging investigator collaborations in the study of the human temporal bone and brain structures subserving the auditory and vestibular systems. The contractor selected for award must have expertise in the administration and/or conduct of otopathology research at the M.D. and/or Ph.D. level. A three-year, cost-reimbursement type contract is anticipated. The solicitation is scheduled for release on or about March 9, 1992 with proposals due April 23, 1992. All responsible sources may submit a proposal that will be considered.

Requests for the Request for Proposals must be directed to:

John P. DeCenzo
Research Contracts Branch
Division of Contracts and Grants
Office of the Director
Building 31, Room 1B44
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-4487

BIOCHEMICAL GENETIC MONITORING OF RODENTS

NIH GUIDE, Volume 21, Number 9, March 6, 1992

RFP AVAILABLE: NCI-CM-37815-30

P.T. 34; K.W. 0780000, 1002019, 1002027, 1003018

National Cancer Institute

The Biological Testing Program (BTP), Development Therapeutics Program (DTP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI), National Institutes of Health (NIH), seeks proposals from organizations having the capabilities to provide a genetic monitoring resource for the BTP. Genetic monitoring for quality assurance will accompany the long-standing efforts in microbiological quality, so that each animal produced from derived stock, under BTP production contracts, is as well defined as possible. Genetic monitoring will be accomplished by biochemical means, i.e., testing for loci involved in producing cellular enzyme or protein variants.

It is anticipated that one contract will be awarded for this effort, as a result of this Request for Proposals (RFP), for a period of 60 months. This RFP is a recompetition of the "Biochemical Genetic Monitoring of Rodents" project being performed by Texas A & M University. RFP No. NCI-CM-37815-30 will be available on or about March 9, 1992, by written request to:

Ms. Elas B. Carlton
Contract Specialist, Research Contracts Branch
Treatment Contracts Section
National Cancer Institute
Executive Plaza South, Room 604
9000 Rockville Pike
Rockville, MD 20892
Telephone: (301) 496-8620

The deadline for submission of proposals will be April 21, 1992. Requests for the RFP must cite the above number. No collect calls will be accepted.

COOPERATIVE AGREEMENT FOR A MULTI-SITE TREATMENT STUDY OF ATTENTION-DEFICIT HYPERACTIVITY DISORDER/ATTENTION DEFICIT DISORDER

NIH GUIDE, Volume 21, Number 9, March 6, 1992

RFA AVAILABLE: MH-92-03

P.T. 34, AA; K.W. 0404004, 0720010, 0414014

National Institute of Mental Health

Application Receipt Date: May 19, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN "INQUIRIES" BELOW.

PURPOSE

Attention-Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD), a syndrome of inattentiveness, impulsiveness, and over-activity, is perhaps the most prevalent of Axis I childhood psychiatric disorders, at least among referrals to child mental health clinics. Although many treatments have been advocated and used, none alone seem completely satisfactory, especially over extended periods of time. The non-uniformity of hyperactive children's responses to each treatment and combination of treatments is probably related to the extensive associated comorbidity (e.g., conduct disorder, depression, anxiety, learning disorder). The National Institute of Mental Health (NIMH) Multimodal Treatment Study of ADHD/ADD to be developed by this cooperative agreement will address a range of treatment issues concerning ADHD emphasized by the Institute of Medicine study "Research on Children and Adolescents with Mental, Behavioral, and Developmental Disorders," the NIMH "National Plan for Research on Child and Adolescent Mental Disorders," the "Healthy People 2000," and "Healthy Children 2000" objectives in the area of mental disorders in children and adolescents, and the existing literature. This will be a five-year, multi-site collaborative study with the intention of considering further follow-up.

HEALTH PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority objectives. Of the 300 such objectives, 170 concerning children and adolescents have been collected into "Healthy Children 2000." This RFA, Cooperative Agreement for a Multi-site Treatment Study of Attention-Deficit Hyperactivity Disorder/Attention Deficit Disorder, is related to the priority area of research on "appropriate biomedical and psychosocial interventions." A copy of "Healthy People 2000" (Full Report: Stock Number 017-001-00474-0, or the Summary Report: Stock Number 017-001-00473-1) may be obtained from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325; telephone 202-783-3238.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, public and private, non-profit and for-profit organizations such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Applications are encouraged from women and minority investigators.

MECHANISM OF SUPPORT

Support of this collaborative study will be through cooperative agreements (U01). Although awardees will be primarily responsible for the conduct of the study, there will be (1) collaboration among the participating sites and (2) programmatic involvement of NIMH staff above and beyond the levels required for the program administration of individual research grants (R01). Applicants are expected to recommend a tentative design with specific methods, instruments, psychosocial treatments, and psychopharmacological protocol. However, during year 1, successful applicants will negotiate a common design/protocol through the committee mechanism explained in the RFA. Applicants must, therefore, recognize that the final common protocol to be implemented is likely to differ from that which has been submitted and reviewed.

This RFA is a one-time solicitation with a special receipt date of May 19, 1992. It is anticipated that four to six sites will be funded for five years starting September 1992. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary PHS peer review procedures.

FUNDS AVAILABLE

It is anticipated that up to \$2.5 million per year in total costs will be available for five years to support up to six new cooperative agreement awards under this announcement during fiscal year 1992, subject to the availability of funds. Funding is dependent on the receipt of a sufficient number of applications of high scientific merit. Funding in future years will depend upon annual appropriations.

RESEARCH OBJECTIVES

The objectives include clarification of treatment issues subsumed by the question: Under what circumstances and patient characteristics (e.g., comorbid conditions, family socioeconomic background, metabolic/nutritional status, neurophysiological/neuropsychological status, gender, age) do which treatment combinations (specific medication, behavior therapy, parent training, school-based intervention), have what impacts (improvement, stasis, deterioration) on what domains of child functioning (cognitive, academic, behavioral, physical, peer relations, family relations), for how long (short vs. long term), to what extent (effect sizes, normal vs. pathological range), and why (processes underlying change)? This complex question easily generates multiple hypotheses to be tested, of which several examples are listed in the RFA. Especially emphasized in the study objectives are the effects of comorbid conditions on treatment response.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

Applicants are to use the grant application form PHS 398 (rev. 9/91). The number and title of this RFA, "Cooperative Agreement for a Multi-site Treatment Study of ADHD, MH-92-03," must be typed in item number 2 on the face page of the PHS 398 application form. Application kits containing the necessary forms and instructions may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following office may be contacted for the necessary application material:

Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-05
Rockville, MD 20857
Telephone: (301) 443-4414

Applications submitted for the receipt date of May 19, 1992, must be complete and contain all information needed for initial and Advisory Council review. If an application is received after that date, it will be returned to the applicant. No subsequent addenda will be accepted unless specifically requested by the Scientific Review Administrator of the review committee.

REVIEW CONSIDERATIONS

Applications judged to be responsive to the RFA will be evaluated for scientific and technical merit by a peer review group convened by the Division of Extramural Activities, NIMH, in accordance with the standard NIMH peer review procedures.

- o The scientific merit and mental health significance of the proposed research including the adequacy with which the applicant addresses the objectives and methodological and other issues detailed in the RFA.

- o The relevant expertise and qualifications of the Principal Investigator and other proposed staff/collaborators.
- o Documentation of the adequacy of facilities, resources, and subject pool.
- o Appropriateness of the proposed budget and duration/pacing in relation to the proposed research.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications responsive to this RFA. The following will be considered in making funding decisions: quality of the application as determined by peer review; availability of funds; program balance; and relevance to the objectives of the RFA.

INQUIRIES

Potential applicants may obtain a copy of the "NIMH National Plan for Research on Child and Adolescent Mental Disorders" from:

Information Resources and Inquiries Branch
National Institute of Mental Health
Parklawn Building, Room 15C-05
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4513

Potential applicants are encouraged to seek pre-application consultation (telephone, written, or personal appointment). Brief answers, extended consultation, and copies of the RFA may be obtained from:

Child and Adolescent Disorders Research Branch
Division of Clinical Research
National Institute of Mental Health
Parklawn Building, Room 10-104
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-5944
FAX: (301) 443-4045

Inquiries about grants management and fiscal issues may be directed to:

Stephen J. Hudak
Chief, Grants Management Section
National Institute of Mental Health
Parklawn Building, Room 7C-05
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4456

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.242. Awards are made under the authorization of the Public Health Service (PHS) Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99- 158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

NOVEL NON-IONIZING RADIATION TECHNOLOGIES FOR BREAST CANCER IMAGING

NIH GUIDE, Volume 21, Number 9, March 6, 1992

PA NUMBER: PA-92-45

P.T. 34; K.W. 0706030, 0715035, 0735000, 0607024

National Cancer Institute

PURPOSE

The National Cancer Institute (NCI) through the Diagnostic Imaging Research Branch (DIRB) of the Radiation Research Program seeks grant applications to conduct multidisciplinary research in the area of novel non-X-ray technology development and evaluation for improved breast cancer imaging. This Program Announcement encompasses a full range of studies from basic technology and instrumentation development through pre-clinical and clinical evaluation.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives

of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Novel Non-Ionizing Radiation Technologies for Breast Cancer Imaging, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202- 783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, public and private, nonprofit and for-profit organizations such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

This program will be supported by the individual research grant (R01) and the First Independent Research and Transition (FIRST) Award mechanisms. Awards will be administered in accordance with the Public Health Service Policy as described in the PHS Grant Policy Statement, DHHS Publication No. (OASH) 90-50,000 revised October 1, 1990.

RESEARCH OBJECTIVES

The goal of this Program Announcement is to stimulate development and validation of novel non-ionizing radiation technologies and imaging methodologies for the improved diagnosis and characterization of breast cancer.

Background

Current data indicate that conventional mammography is a mature imaging technology producing high-quality images in the majority of patients. Indeed, conventional mammography has been shown to be an accepted problem-solving and an effective screening tool in older women (age category over 50 years), resulting in a 30 percent mortality reduction in these patients. However, recent data indicate that novel technologies, such as conventional magnetic resonance imaging (MRI) and ultrasound, may provide important additional diagnostic information if the detected lesions need to be characterized (e.g., cystic vs. solid mass) and/or in younger women and patients with radiodense breast tissue. Further clinical studies are required to define the comparative role and analyze the cost-effectiveness of MRI and ultrasound in breast cancer diagnosis and characterization.

Dynamic contrast-enhanced MRI has been shown to be a promising adjunctive diagnostic tool in the following clinical situations: (1) conventional mammography and physical examination fail to provide diagnosis; (2) the differentiation of dysplasia vs. cancer; (3) dense breast; and (4) small lesions.

Advanced MRI and ultrasound technologies appear to have an important potential for quantitative characterization of tumor biology. Novel ultrasound technologies, such as high frequency systems, modern pulse echo/color flow, and 2D/3D imaging, may improve image quality and provide improved anatomic and physiologic information. Novel MR techniques, such as magnetization transfer approach, diffusion/perfusion imaging, magnetic resonance spectroscopy and electron spin resonance, will provide additional quantitative biochemical, biophysical, and physiologic parameters for breast cancer characterization in order to optimize treatment planning.

Further, a number of novel imaging techniques (e.g., optical, microwave, thermal) are currently under development. Indeed, recent reports indicate that the ballistic optical imaging technique, while highly experimental at this stage, can detect structures in vitro as small as 200 microns. Further studies are required to advance this technology for in vivo use.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans [including American Indians or Alaskan Natives], Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders

or conditions, including not but limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

The research grant application form PHS 398 (revised 9/91) is to be used in responding to this Program Announcement. These forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892, telephone (301) 496-7441.

The Program Announcement number and title must be typed on line 2 of the face page of the application form.

Submit a signed, typewritten original of the application, including the Checklist, and five signed, exact photocopies in one package to the address below. The photocopies must be clear and single sided.

DIVISION OF RESEARCH GRANTS

National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applications will be accepted on the standard receipt dates for new applications: October 1, February 1 and June 1. If the application submitted in response to this program announcement is substantially similar to a grant application already submitted to the NIH for review, but has not yet been reviewed, the applicant will be asked to withdraw either the pending application or the new one. Simultaneous submission of identical applications will not be allowed, nor will essentially identical applications be reviewed by different review committees. Therefore, an application cannot be submitted in response to this announcement that is essentially identical to one that has already been reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of this Program Announcement and inquiries about whether or not specific proposed research would be responsive are encouraged and are to be directed to:

Faina Shtern, M.D.
Chief, Diagnostic Imaging Research Branch
Radiation Research Program
National Cancer Institute
Executive Plaza North, Suite 800
Bethesda, MD 20892
Telephone: (301) 496-9531

The Program Director welcomes the opportunity to clarify any issues or questions from potential applicants.

Direct inquiries regarding fiscal matters to:

Marian F. Focke
Grants Administration Branch
National Cancer Institute
Executive Plaza South 242
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 46

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.395, Cancer Treatment Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A. (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285), and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

RESEARCH ON THE PREVENTION OF ALCOHOL ABUSE AMONG YOUTH

NIH GUIDE, Volume 21, Number 9, March 6, 1992

PA AVAILABILITY: PA-92-46

P.T. 34, AA; K.W. 0404003, 0745027

National Institute on Alcohol Abuse and Alcoholism

THE PROGRAM ANNOUNCEMENT DESCRIBED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE PROGRAM ANNOUNCEMENT FROM THE CONTACT NAMED IN INQUIRIES BELOW.

PURPOSE

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) wishes to encourage new and creative research on the development and testing of strategies to prevent alcohol abuse among youth including children, adolescents, and young adults.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Research on the Prevention of Alcohol Abuse Among Youth, is related to the priority areas of decreasing morbidity and mortality associated with the drinking of alcohol by adolescents and young adults. Prevention strategies focus on delaying the age of initiation for alcohol use among adolescents; reducing the incidence and prevalence of alcohol abuse among youth; and testing interventions that will result in a reduction in motor vehicle crashes and fatalities associated with alcohol use. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (Telephone: 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign non-profit and for-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

MECHANISMS OF SUPPORT

Research support may be requested through applications for a research grant (R01), small grant (R03), and First Independent Research Support and Transition (FIRST) Award (R29). Specialized announcements for the FIRST Award program (R29) and the small grant program (R03) are available from the National Clearinghouse for Alcohol and Drug Information (NCADI), P.O. Box 2345, Rockville, MD 20852, telephone (301) 468-2600.

RESEARCH OBJECTIVES

Although other ideas are welcome, the NIAAA is especially interested in grant applications directed at norm-setting and norm-enforcement by parents and families, primary-care physicians and their staffs, youth peer groups, elementary and secondary public and private schools and/or school systems, colleges and universities, and/or other community organizations that have direct contact with children, adolescents, and young adults. Parents, schools, police, and other community groups set and enforce norms concerning alcohol use by youth. In addition, peer groups set and enforce drinking norms in informal settings. This announcement encourages research that examines links between the social setting and enforcement of norms by peer groups, parents and families, educational and legal institutions, and community organizations to prevent abusive drinking by youth. Applications that propose interventions targeted toward combinations of these groups may also be submitted.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF ADAMHA POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

For projects involving clinical research, ADAMHA requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included or adequately represented in the study populations for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

All applications for clinical research submitted to ADAMHA are required to address these policies. ADAMHA funding components will not award grants that do not comply with these policies.

APPLICATION PROCEDURES

Applicants are to use the grant application form PHS 398 (rev. 9/91). The number and title of this program announcement, "PA-92-46, Research on the Prevention of Alcohol Abuse Among Youth," must be typed in line 2 on the face page of the PHS 398 application form.

Application kits containing the necessary forms and instructions may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following office may be contacted for the necessary application material:

National Clearinghouse for Alcohol and Drug Information
P.O. Box 2345
Rockville, MD 20852
Telephone: (301) 468-2600

The signed original and five permanent, legible copies of the completed application must be submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary PHS grant programs. Applications received under this announcement will be assigned to an Initial Review Group (IRG) in accordance with established PHS Referral Guidelines. The IRG, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit. Notification of the review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by an appropriate national advisory council. Only applications recommended by the Council may be considered for funding.

AWARD CRITERIA

Applications recommended by a national advisory council will be considered for funding on the basis of overall scientific and technical merit of the research as determined by peer review, program needs and balance, and availability of funds.

INQUIRIES

Potential applicants are encouraged to seek preapplication consultation by contacting the program official below. Requests for copies of the complete program announcement may be directed to:

Phyllis A. Langton, Ph.D.
Prevention Research Scientist
Prevention Research Branch
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.273. Awards are made under the authority of Sections 301 and 510 of the Public Health Service Act, as amended (42 USC 241 and 290bb). Federal

regulations at 42 CFR Part 52, "Grants for Research Projects," and Title 45 CFR Parts 74 and 92, generic requirements concerning the administration of grants, are applicable to these awards. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NEUROFIBROMATOSIS

NIH GUIDE, Volume 21, Number 9, March 6, 1992

PA NUMBER: PA-92-47

P.T. 34; K.W. 0715008, 1002004, 1002058, 0765035, 0755020

National Institute of Neurological Disorders and Stroke
National Cancer Institute

PURPOSE

The National Institute of Neurological Disorders and Stroke (NINDS) and the National Cancer Institute (NCI) encourage the submission of research grant applications in basic science and clinical investigations concerning all aspects of neurofibromatosis including molecular genetics, cell biology, pathophysiology, development of new animal models, diagnosis, and treatment.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priorities. This program announcement, Neurofibromatosis, is related to the priority areas of chronic disabling conditions and cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: No. 017-001-474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone: 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged. However, foreign institutions are not eligible to apply for the First Independent Research Support and Transition (FIRST) Award (R29).

MECHANISMS OF SUPPORT

Applicants may use the Research Project Grant (R01), Research Program Project (P01), Research Center Grant (P50), and FIRST Award (R29). Prospective applicants are encouraged to communicate with the NINDS and NCI program contacts listed at the end of the announcement regarding the appropriate funding mechanism.

RESEARCH OBJECTIVES

Neurofibromatosis 1 (NF1), or von Recklinghausen's disease, is an autosomal dominant inherited disorder affecting the central and peripheral nervous system. Its prevalence is about 1 in 4,000. It is characterized by cafe au lait spots of the skin, neurofibromas, schwannomas, intracranial tumors, Lisch nodules, and other associated lesions.

The NF1 gene on chromosome 17 has been cloned. Further studies are needed to characterize its gene product. The normal NF1 gene product may be an anti-oncogene that suppresses the ras oncogene. When disinhibited by the mutation of the NF1 gene, the ras oncogene may cause tumor formation.

At the present time, molecular genetic screening is of limited usefulness in counseling and clinical management of NF1. It requires familial markers (not available for all families or for sporadic cases), and it cannot predict the rate or degree of progression of the disorder in a given diagnosed individual.

Neurofibromatosis 2 (NF2), or bilateral acoustic neurofibromatosis, is an autosomal dominant disorder associated with vestibular schwannomas and other schwannomas, meningiomas, ependymomas, gliomas, and posterior subcapsular cataracts. Its prevalence is about 1 in 40,000.

The NF2 gene has been mapped to chromosome 22 in one published family. The gene has not yet been isolated. It is believed to normally function as a tumor suppressor gene.

Multidisciplinary and collaborative studies of neurofibromatosis are encouraged. Examples are given below, but applications are not limited to these areas of research:

- o Improvement of diagnostic criteria and tests for use in genetic counseling and clinical management of NF1, NF2, and atypical or variant NF.
- o Development of transgenic animal models to study the pathogenesis of NF1, NF2, and associated tumors.
- o Studies to explain the variability of clinical expression of NF1 and NF2. Can genotype-phenotype correlations be made in an individual patient? Is the phenotype modulated by modifying genes? Does the expression of these disorders in a given individual depend not only on the precise genetic defect but also on

the individual's sex, on the parent from whom the gene defect was inherited, or on other factors?

- o Identification and analysis of the NF1 and NF2 gene products and their functions in normal cellular physiology, in the pathophysiology of neurofibromatosis, and in tumorigenesis.
- o Basic studies of neurodevelopmental mechanisms affected by neurofibromatosis such as neural crest cell migration and differentiation.
- o Understanding the nature and neurobiologic basis of the cognitive impairment associated with NF1.
- o Development and assessment of new and innovative therapeutic strategies for the many associated manifestations of NF1 and NF2.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Section 2, A-D of the research plan AND summarized in Section 2, E, Human Subjects. Applicants/offerees are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed and the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) according to instructions contained in the application kit. Application kits are available from most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, MD 20892, telephone 301-496-7441.

Check "yes" in item two on the face sheet of the application and type "Neurofibromatosis, and PA-92-47."

Applicants for the P01 or P50 must use the application format as described in the NINDS pamphlet, "Application Guidelines: Program Project and Clinical Research Center Grants," or the NCI pamphlet, "Program Project Grant of the National Cancer Institute," which may be obtained from the contacts listed under Inquiries.

Deadlines for the receipt of applications are February 1, June 1, and October 1. The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be judged on scientific merit and program relevance in accordance with NIH policy and procedures involving peer review. An initial review will be made by an appropriate study section of the Division of Research Grants for research grants and FIRST awards, and by an appropriate Institute or Center committee for program project and center applications. A second level of review will be made by an appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be used in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

For further information regarding this announcement, potential applicants may write or call:

Philip H. Sheridan, M.D.
Developmental Neurology Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 8C10
Bethesda, MD 20892
Telephone: (301) 496-6701

or

Michael R. Martin, Ph.D.
The Tumor Biology Program
National Cancer Institute
6120 Executive Plaza South, Room 630
Rockville, MD 20852
Telephone: (301) 496-7028

For fiscal and administrative inquiries regarding this announcement, potential applicants may write or call:

Gary P. Fleming, J.D.
Grants Management Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 1004
Bethesda, MD 20892
Telephone: (301) 496-9231

or

Robert Hawkins
Grants Administration Branch
National Cancer Institute
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Rockville, MD 20852
Telephone: (301) 496-7933

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.853, Clinical Research Related Neurological Disorders and 93.854, Biological Basis Research in the Neurosciences. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-150, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

THE HEREDITARY ATAXIAS INCLUDING MACHADO-JOSEPH DISEASE

NIH GUIDE, Volume 21, Number 9, March 6, 1992

PA: PA-92-48

P.T. 34; K.W. 1002019, 0765035, 1002058, 0745020, 0785055

National Institute of Neurological Disorders and Stroke

PURPOSE

The Convulsive, Developmental, and Neuromuscular Disorders Program of the National Institute of Neurological Disorders and Stroke (NINDS) encourages the submission of applications for research grants related to the hereditary ataxias including Machado-Joseph Disease (MJD). The NINDS invites grant applications to support research on all aspects of this heterogeneous group of inherited degenerative disorders including pathophysiology, epidemiology, molecular genetics, diagnosis, and treatment.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention goals of "Healthy People 2000," a PHS-led national activity for setting priorities. This program announcement, The Hereditary Ataxias Including Machado-Joseph Disease, is related to the priority areas of physical activity and fitness, and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: No. 017-001-474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone: 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged. However foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) Award (R29).

MECHANISMS OF SUPPORT

Applicants may use the Research Project Grant (R01), Research Program Project (P01), Research Center Grant (P50), and First Independent Research Support and Transition Award (R29). Prospective applicants are encouraged to communicate with the NINDS program contact listed at the end of the announcement regarding the appropriate funding mechanism.

RESEARCH OBJECTIVES

The hereditary ataxias, in general, encompass a variety of degenerative disorders, interchangeably referred to as spinocerebellar degenerations, that are difficult to classify due to limited knowledge of etiologic factors, variability of clinical manifestations, and limited correlation between clinical signs and postmortem changes. Onset of system degenerations may span a lifetime but often begin in the first to second decade of life.

In the past, the hereditary ataxias have been categorized into predominantly spinal, spinocerebellar, and pure cerebellar forms based on a "typical" clinical picture and age of onset of signs and symptoms. Familial inheritance has been clearly shown in many of these disorders, and families may exhibit x-linked recessive, autosomal dominant or recessive patterns.

The predominant presentation is the development of a chronic, progressive ataxia with variable signs and symptoms referable to the cerebellum and its afferent and efferent pathways, posterior columns, pyramidal tracts, basal ganglia, brainstem nuclei, other brain regions and peripheral nerve. In addition, there may be visual impairment (optic atrophy, pigmentary retinal degeneration), hearing dysfunction (sensory neural hearing loss), dermatological manifestations, hypogonadism, dementia, and, in some disorders, definable biochemical or genetic abnormalities.

Though the clinical picture may be consistent within a family, there may be gradations of presentation that result in overlap and somewhat arbitrary distinctions, between disease entities. Examples of diseases addressed in this announcement include MJD, hereditary spinocerebellar ataxias (Friedreich's Syndrome), hereditary cerebellar ataxias, ataxia-telangiectasia, hereditary spastic paraparesis, Roussy-Levy and Marinesco-Sjogren syndrome, abetalipoproteinemia (Bassen-Kornzweig syndrome), Refsum's disease and dyssynergia cerebellaris myoclonica (Ramsay Hunt syndrome). One representative example of the hereditary ataxias, MJD, is an autosomal dominant, hereditary, progressive motor system disease initially identified among families of Portuguese-Azorean descent but now identified worldwide in many ethnic groups. Three main syndromes have been described based on heterogeneity of clinical expression felt to be phenotypic variabilities of a single gene mutation. The progressive neurological deficits result in death from debilitation within 10 to 30 years of onset. To date, there is no genetic or biochemical marker. There is no effective treatment or cure. Prevention depends on limited genetic counseling of identified families.

In June 1991 an NINDS-sponsored international workshop on Research Initiatives on Machado-Joseph Disease explored issues on the description of the clinical spectrum and epidemiology, neuropathology and neurochemistry, molecular genetics, and improving diagnosis and treatment. Research needs and priorities include more precise diagnosis, elucidation of the pathophysiology, molecular genetics, and treatment of this, and similar ataxic disorders.

The goals of this announcement are to stimulate research in both basic science and clinical aspects related the hereditary ataxias including MJD. The scope of this program encompasses both animal and human studies that would utilize a variety of experimental approaches and methods. A major emphasis is to expand research of the underlying mechanisms of early brain degeneration inherent to each of the hereditary ataxias. Multidisciplinary and collaborative studies are encouraged. Examples of areas of potential research include, but are not limited to, the following:

- o Standardized definitions and diagnoses: research criteria and classifications.
- o Longitudinal studies that describe the natural history of disease and that provide complete descriptions of clinical signs and symptoms of disease within families.
- o Neuroepidemiological studies of at-risk populations.
- o Experimental animal models with cerebellar system degenerations that have features consistent with neuropathological changes of the disorder.
- o Collaborative neuropathological studies on affected and at-risk populations utilizing a variety of techniques that better identify the first cells to be affected, the progression of the disease, and the type of dysfunction that occurs in those cells prior to death.
- o Evaluate possible therapeutic interventions to retard the progression of disease.
- o Neurochemical studies to define pathophysiology and to enable premorbid diagnosis or risk determination.
- o Studies utilizing neurodiagnostic and neuroimaging modalities.
- o Collaborative efforts on genetic research with an interchange of families, probes, and results towards identifying the defective gene(s) and gene products.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

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APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) according to instructions contained in the application kit. Application kits are available from most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, MD 20892, telephone 301-496-7441.

Check "yes" in item two on the face sheet of the application and type "The Hereditary Ataxias Including Machado-Joseph, PA-92-48."

Applicants for the P01 or P50 must use the application format as described in the NINDS pamphlet, "Application Guidelines: Program Project and Clinical Research Center Grants," that may be obtained from the contacts listed under INQUIRIES.

Deadlines for the receipt of applications are February 1, June 1, and October 1. The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

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AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be used in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

For further information regarding this announcement, potential applicants may write or call:

Giovanna M. Spinella, M.D.
Developmental Neurology Branch
Division of Developmental, Convulsive, and Neuromuscular Disorders
National Institute of Neurological Disorders and Stroke
Federal Building, Room 820
Bethesda, MD 20892
Telephone: (301) 496-5821

For fiscal and administrative inquiries regarding this announcement, potential applicants may write or call:

Gary P. Fleming, J.D.
Grants Management Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 1004
Bethesda, MD 20892
Telephone: (301) 496-9231

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.853, Clinical Research Related Neurological Disorders and 93.854, Biological Basis Research in the Neurosciences. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-150, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

RESEARCH ON FERTILITY AND FERTILITY-RELATED BEHAVIOR

NIH GUIDE, Volume 21, Number 9, March 6, 1992

PA NUMBER: PA-92-49

P.T. 34; K.W. 0413002, 0413001, 0404000, 0755020

National Institute for Child Health and Human Development

PURPOSE

The National Institute for Child Health and Human Development invites applications for demographic and behavioral research on fertility, the proximate determinants of fertility, and the causes and consequences of fertility-related behaviors.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Research on Fertility and Fertility-Related Behavior, is related to the priority areas of family planning and sexually transmitted diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000 (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, private research firms, units of State and local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged. Applicants for First Independent Research Support and Transition (FIRST) Awards (R29) must meet specific eligibility requirements. In addition, foreign applicants are not eligible for the FIRST Award.

MECHANISM OF SUPPORT

Mechanisms available for the support of this program include research project grants (R01), and the FIRST Award (R29).

RESEARCH OBJECTIVES

Summary

This announcement invites behavioral and demographic research on fertility, the proximate determinants of fertility, and the causes and consequences of fertility-related behaviors. The goal is to extend the understanding of fertility and fertility-related behaviors in two important ways: first, by explaining recent developments in fertility and their relationships to other social changes; and second, by developing and testing new and expanded models at either the individual or aggregate level to explain variation in fertility and related behaviors. In many instances, the success of this research may depend on the development of new theoretical approaches and/or the development of improved and innovative methods for measuring fertility-related behaviors and the processes that influence them.

Background

Research on the causes and consequences of fertility behavior has occupied demographers since population science emerged as a field of study. During the twentieth century this field has encompassed simple descriptions of population levels, trends and differentials in fertility as well as the development of complex causal models explaining individual fertility behavior. In the past decade, research on fertility has been shaped by several factors, including trends in fertility rates, a changing societal context for childbearing, and the development of data and statistical tools for testing interdisciplinary and multilevel models. During the 1980s, fertility rates remained stable throughout most of the developed world and declined to varying degrees in the developing countries. At the very end of the decade, however, U.S. fertility showed signs of a renewed upturn, particularly at the younger and older ages. Recent decades have witnessed a dramatic increase in the proportion of all births that occur out of wedlock, from 5 percent in 1960 to 27 percent in 1989. This change has paralleled delays in the age of first marriage and increases in female labor force participation. Scientists' ability to develop empirical models of the complex factors affecting fertility was greatly enhanced by developments in statistics, computer technology, and a proliferation of longitudinal and cross-sectional data sets. However, data limitations still hamper the integration and extension of much existing research.

Research Sought

Research applications submitted in response to this announcement may focus on any aspect of human fertility and may be grounded within a broad range of disciplinary frameworks. These may include but are not limited to sociology, economics, psychology, anthropology, biology, and public health. Interdisciplinary approaches are encouraged. Research on fertility may address any relevant aspect, including but not limited to levels (numbers of births and fertility rates), birth timing, wanted and unwanted childbearing, childbearing in and out of wedlock, and variability in these factors within and across populations. The proximate determinants of fertility include contraceptive practice, union formation and sexual activity, fecundity, and pregnancy outcomes. The following topics have been highlighted as promising areas for research (but applications for grants to support research on other aspects of fertility are welcome):

- a. In the U. S. and other developed countries, sexual activity and childbearing have become increasingly disconnected from legal marriage. Trends in premarital sexual activity, cohabitation and non-marital childbearing have been well documented, but their causes and, to a lesser extent, their implications are poorly understood. What underlies the early sexual involvement of many young people and the choice of non-marital childbearing by increasing proportions of young adults? What factors contribute to the postponement of sexual activity and the choice and maintenance of a stable union as a context for child rearing? Research is needed to examine the impact of economic and social factors in shaping alternative strategies for childbearing and child rearing and the family and contextual processes that shape norms and values about sexual and reproductive

behavior. Further research is also needed on the implications of current trends for children, adults, and society.

b. Lack of information on male behaviors related to family formation creates a significant gap in fertility research. Research on the determinants and consequences of male fertility and fertility-related behaviors is needed to complement knowledge gained from research focused on women alone. Research focusing on the couple as the relevant unit in fertility analysis is also encouraged. In order to advance our understanding in this area, scientists are encouraged to develop innovative methods of obtaining non-biased samples, and samples that capture unmarried as well as married couples.

c. Research is needed on the relationship between parenthood and other familial and nonfamilial roles. Specific topics include the interrelation between processes of role choice, change, and accommodation and fertility, and factors, such as child care and flexibility in the workplace, that ease or exacerbate role conflict. We encourage development of new approaches to capturing the dynamic aspects of entries to and exits from different adult roles, to understanding the factors contributing to variability in life course trajectories, and to accounting for selection processes in examining the consequences of different trajectories for fertility behavior and other life domains.

d. The influence of context on fertility and fertility related behavior requires further study. Both normative and structural aspects of context may influence fertility. Context may be variously interpreted to mean geographical context (the community, place of residence or work), social contexts (such as the family, sexual partnership, peer group), or institutional contexts (the church, workplace or school). Policy-relevant variables and program inputs may also be viewed as contextual factors. Innovative research designs for capturing contextual effects and accounting for the effects of choice of context are needed to advance research on this topic.

e. Research is needed on the determinants of both short term and long term trends in fertility. A variety of explanations have been advanced to account for short run variations in fertility levels in the developed world, but none have received consistent support. Further work is needed to improve our understanding of the interrelations between fertility and social and economic trends. Our perspective on the causes of long-run trends may be improved by examining the interrelationships between family and institutional change and fertility decline in a variety of settings. Recent advances in economic growth theory have suggested a connection between fertility and economic growth that is modulated by human capital and institutional factors. Empirical testing of these relationships is encouraged.

f. Extension of existing research on the factors accounting for the continuing high rate of unintended pregnancy is encouraged. Topics of current interest include how characteristics of couples and partners affect contraceptive practice; how sexual behavior and contraception contribute to defining, and are themselves shaped by, the nature and meaning of relationships; the impact of concerns about sexually transmitted disease on sexual and contraceptive decision-making; the determinants of consistent and accurate method use; structural factors affecting access to contraceptive methods and/or motivation to avoid pregnancy; and issues related to measuring the "intendedness" of a pregnancy.

g. Research on the outcomes of unintended pregnancy is also encouraged. Relevant topics include the determinants and consequences of giving birth, of parenting versus relinquishing for adoption, and of marriage and alternative family living arrangements. Innovative means must be devised to avoid biased samples in designing this research.

h. Motivational factors in fertility decision-making, the determinants of fertility motivation and desires, and the process through which individual motivations are translated into couple fertility decisions also deserve study. Relevant motivational factors may include not only those directly related to childbearing but also those related to other adult behaviors such as union formation and nonfamilial roles and aspirations. Advances in developing measures that capture multiple dimensions of motivation, that distinguish motivation to become a parent from motivation to prevent pregnancy or birth, and that may be appropriately applied to both men and women need further development, particularly among minority and low income populations.

i. We encourage the extension of biosocial models of fertility and fertility-related behaviors. Existing research in this area has documented the utility of models that incorporate biological, and social, psychological, and economic variables. These models have been employed primarily for studying adolescents and may fruitfully be extended to adult behaviors and to the investigation of the intergenerational transmission of behavioral patterns.

Data Sources

Analysis of existing data is cost-efficient and is strongly encouraged whenever scientific goals can be met. Many data sets relevant to the analysis of fertility and fertility related behaviors are publicly available. Among those relating to the U.S. population are the National Surveys of Family Growth (and predecessors such as the National Fertility Surveys and the Growth of American Families Studies); the National Longitudinal Surveys, Youth Cohort and Child Supplement; the National Survey of Families and Households; the National Longitudinal Study of the High School Class of 1972; High School and Beyond; National Education Longitudinal Study; data from the Decennial Census and Current Population Survey (June supplements); Vital Statistics data; the Panel Study of Income Dynamics; and the Survey of Income and Program Participation. Other relevant data sets may be obtained through The Data Archive on Adolescent Pregnancy and Pregnancy Prevention and the American Family Data Archive. Applicants are encouraged to contact program staff to discuss potential data sources.

New data collection may be necessary whenever existing data resources are not appropriate to the scientific aims of the study. In many cases, methodological components to research may be appropriate for developing improved measures and measurement techniques. If new data collection is proposed, applicants are encouraged to design

protocols and samples that are efficiently tailored to the scientific needs of the project. Scientific sampling procedures are highly desirable to ensure that sample biases do not undercut scientific objectives, but the size and scope of samples may legitimately be limited in a manner consistent with study objectives. Applicants proposing new data collection are encouraged to make their data available for use by other researchers, and should indicate plans for accomplishing this in the application.

STUDY POPULATIONS

Research may focus on U.S. and other developed world populations and subgroups thereof, and on developing settings, as appropriate to the scientific questions being examined. Cross-cultural comparisons may be appropriate to specific scientific objectives.

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerers are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants to cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit.

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441. The title and number of the announcement must be typed in Section 2 on the face page of the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines.

Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that ICD. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review;
- o Availability of funds
- o Program balance

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Christine A. Bachrach, Ph.D.
Center for Population Research
National Institute of Child Health and Human Development
Executive Plaza North, Room 611
6130 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-1174

Direct inquiries regarding fiscal matters to:

Melinda B. Nelson
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 505
6130 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-5481

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.864, Population Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

TECHNOLOGY DEVELOPMENT, MAPPING, AND DNA SEQUENCING IN SUPPORT OF THE HUMAN GENOME PROGRAM

NIH GUIDE, Volume 21, Number 9, March 6, 1992

PA NUMBER: PA-92-50

P.T. 34; K.W. 1215018, 0755045, 1002058, 1004017

National Center for Human Genome Research

PURPOSE

The National Center for Human Genome Research (NCHGR) invites applications to support research that will significantly advance progress toward achieving the scientific goals of the Human Genome Program. A summary of these goals are: completion of a high density genetic linkage map of the human genome; construction of a high-resolution physical map comprised of large contigs (overlapping pieces of cloned DNA); development of a "sequence-tagged site" (STS) map; development of technology to reduce the expense of DNA sequencing significantly below current cost; development of computer tools to manage and provide access to mapping and sequencing data; examination of the legal, ethical, and social implications of the Human Genome Program; and research training.

ELIGIBILITY REQUIREMENTS

Domestic universities, medical colleges, hospitals, and other public, private, and for-profit research institutions, including state and local government units, are eligible. Foreign organizations are also eligible to apply only for the research project grants (R01). Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Support for this program will be through research project grants (R01), pilot projects and feasibility studies

(R21), program project grants (P01), and FIRST Awards (R29). As part of this effort, the NCHGR encourages the support of minority students and faculty interested in the Human Genome Program through the traditional NIH funding mechanisms and through minority supplements to ongoing research grants (see announcement in the NIH Guide for Grants and Contracts, Vol. 21, No. 3, Part 1 of 2, January 24, 1992).

Applications to support large, complex research programs through the center grant mechanism will not be considered under this Program Announcement. Applications for P30 and P50 center grants may respond to the Program Announcement in the NIH Guide for Grants and Contracts, Vol. 18, No. 36, October 13, 1989.

RESEARCH OBJECTIVES

Background

The NIH Human Genome Program is envisioned as a 15-year project that has very specific goals. The NCHGR was established in October 1989 for the purpose of planning and supporting the Human Genome Program at NIH and coordinating the NIH component of this program with those of other Federal agencies and international groups. The goals for the first five years of the U.S. Human Genome Program were established by a joint advisory committee of the NIH and the Department of Energy and are set forth in the document, "Understanding Our Genetic Inheritance - The U.S. Human Genome Project: The First Five Years - FY 1991-1995." (This document is available from the Human Genome Management Information System, Oak Ridge National Laboratory, Oak Ridge, TN 37831-6050; telephone, 615-576-6669). These goals are:

- o construction of high-resolution genetic linkage maps based on DNA markers with a goal of achieving an average spacing of 2 centimorgans and gaps no greater than 5 centimorgans between markers, each of which is identified by an STS (Olson et al., *Science* 245:1434, 1989);
- o construction of high resolution physical maps of chromosomes in which contigs of at least 2 million base pairs are unambiguously ordered and identified by STS spaced about 100,000 base pairs apart;
- o development of new methods for DNA sequencing that significantly reduce the cost and increase the rate of sequencing;
- o development of computer tools, information systems, and strategies for collecting, storing, retrieving, analyzing, interpreting, and distributing large amounts of mapping and sequencing data;
- o examination of legal, ethical, and social implications of the Human Genome Program (see Program Announcement in NIH Guide for Grants and Contracts, Vol. 19, No. 4, January 26, 1990); and
- o research training (see Program Announcement in NIH Guide for Grants and Contracts, Vol. 18, No. 25, July 21, 1989).

The objective of this Program Announcement is to stimulate research that will assist the NCHGR in accomplishing both the short- and long-term scientific goals of the Human Genome Program in the most expeditious and cost-saving manner. This Program Announcement supersedes the one that was published in the NIH Guide for Grants and Contracts, Vol. 19, No. 28, 1990.

In planning research projects, applicants should be cognizant of the following:

Technology Development. Although a number of the techniques currently in use for mapping have proven useful in initial successes in building megabase-size contigs and studying specific genomic regions, it is anticipated that new technologies, strategies and approaches are still needed to reach the final mapping goal of the Human Genome Program most expeditiously and in a cost-effective manner. Similarly, the technology currently available for sequencing and data handling is not capable of supporting the goals of the Human Genome Program in these areas. Therefore, in the first five years of the Human Genome Program, emphasis will be placed on technology development in all phases of mapping, sequencing and informatics. For applications with the primary objective of map construction, those that improve or propose new technology as a significant component will be most competitive. This will also be the case in mapping, sequencing, and informatics applications. Research projects that focus on technology development in the context of a particular disease gene are appropriate if such projects have one or more of the overall objectives of the Human Genome Program as a major research goal.

Collaborative Research. In order to achieve the objectives of the Human Genome Program, collaborations between biologists from various disciplines, including human genetics, as well as between biologists and non-biologists, such as chemists, physicists, information scientists, and engineers, are essential. The NCHGR strongly encourages multidisciplinary collaboration to facilitate progress, especially in technically sophisticated areas.

Duplication/Overlap. A certain amount of duplication in research is inevitable and, in fact, is useful for verifying or validating experimental results. However, given the limited resources and the need to accomplish the goals of the Human Genome Program within the proposed 15-year period, duplication of research, irrespective of funding source, while encouraged, should be kept to a minimum. To assist applicants with respect to what research is supported through the NCHGR, a list of the Human Genome Program grant portfolio is available to potential applicants.

Sharing of Materials and Data. The sharing of materials and data in a timely manner is essential for progress towards the goals of the Human Genome Program, to avoid unnecessary duplication, and to facilitate research in other areas of biomedical research. The Public Health Service (PHS) policy requires the sharing of resources at the time of publication. For some projects that will be supported by the NCHGR, this policy is not sufficient because certain kinds of data may not be published in their entirety, while some information or

resources need to be shared more rapidly than at the time of publication. Because the type of research will dictate the conditions under which data and materials should be shared, applicants should, in their applications, discuss their plans for sharing data and materials and depositing data and materials to appropriate repositories. It is expected that, whenever appropriate, resources such as cell lines, probes, and sequence data, will be deposited expeditiously in public repositories.

Investigators may request funds to defray the costs of sharing materials and submitting data to repositories in their applications. However, such requests must be adequately justified. For applications assigned to the NCHGR, the plans for sharing will be reviewed for adequacy by NIH staff and the National Advisory Council on Human Genome Research prior to award of a grant.

Animal Models. Research involving model systems will contribute greatly to the Human Genome Program. The five-year plan includes, as one of its goals, the support of mapping and sequencing of the DNA of five specific organisms: *E. coli*, *S. cerevisiae*, *D. melanogaster*, *C. elegans*, and the laboratory mouse. The Human Genome Program is, therefore, interested in promoting research using these organisms. However, research projects involving other model organisms may also contribute significantly to the goals of the Human Genome Program. Thus, applicants may propose to study model systems other than those listed. In those cases, the choice of organism must be justified in terms of the overall objectives of the Program. Whereas the "Research Objectives" described below do not specify research to be conducted on model organisms, such research is encouraged.

Pilot Projects or Feasibility Studies. The NCHGR is interested in supporting scientifically sound projects that are novel, creative, or high risk/high payoff. Applicants who seek funding to support such research and need limited funding to conduct preliminary studies should submit applications in response to the Program Announcement "Pilot Projects or Feasibility Studies for Genomic Analysis," (see NIH Guide for Grants and Contracts, Vol. 19, No. 28, July 27, 1990).

Specific Research Objectives

In order to achieve the goals of the Human Genome Program, applications that propose to develop new approaches and strategies to mapping and sequencing problems, as well as those that propose creative, novel, high-risk/high-payoff strategies, are highly encouraged. All researchers applying for support should (1) address how the proposed research will help accomplish the five-year goals; (2) discuss new approaches and/or technology as part of the mapping or sequencing strategy; (3) approach the problem in a comprehensive manner, irrespective of the size of the project (e.g., in constructing a physical map of a particular chromosome, emphasis should be placed on constructing fully connected contigs, i.e., overlapping units of cloned DNA, rather than just mapping available probes); (4) demonstrate that there are adequate plans for: (a) data management, (b) interacting and collaborating with the rest of the scientific community working on similar or related objectives, and (c) making data and resources publicly available in a timely manner; and (5) in the case of specific mapping and technology development applications, address how the proposed research project will relate to or augment existing research efforts.

Genetic Linkage Maps

High-density genetic linkage maps are important for attainment of the goals of the Human Genome Program as they will facilitate (1) the identification of gene locations and (2) the construction of a complete physical map by allowing contigs (overlapping clones of DNA) to be ordered with respect to one another.

The Human Genome Program has set as one of its goals during the first five years the creation of a 2 to 5 centimorgan human genetic linkage map. A map of this resolution would require 1500 to 2000 informative markers evenly spaced along the genome; in addition each DNA marker would be defined by a unique STS. An STS is defined as a DNA marker that is unique in the genome and can be detected by the polymerase chain reaction. The STS concept has been promoted as a device that will allow mapping data from different laboratories and from different types of maps to be merged or assimilated.

To facilitate completion of a high-density genetic map, applications are encouraged in the following areas:

- o Development of methods to rapidly and efficiently isolate, identify, and map highly informative markers.
- o Expansion of the maps of individual chromosomes with the goal of achieving a high-resolution map comprised of DNA markers with an average spacing of 2 centimorgans and gaps no greater than 5 centimorgans, and with each marker identified by an STS. Applications are particularly encouraged for projects addressing those chromosomes or regions of chromosomes where there are presently few markers or those approaching the completion of the genetic map using a genomic, rather than a chromosome-by-chromosome, strategy.
- o Improvement of methods for linkage analysis and ordering of markers.
- o Closure methods targeted to finding and mapping markers within gaps in existing maps.
- o Technology development to accelerate completion of a 2-5 centimorgan map of the human genome.

Physical Maps

A physical map is a very useful resource because it is the basis for characterizing and isolating individual genes or other DNA regions of interest and is a prerequisite for large-scale DNA sequencing. There are several types of physical maps including cytogenetic maps, long-range restriction maps and contig maps. To facilitate the construction of a complete physical map, at least two aspects of mapping need to be improved: (1) the length of a DNA segment that can be routinely covered by a single contig or spanned by a set of closely spaced ordered markers must be increased and (2) methods for closure or filling in the gaps between contigs also need

to be developed or improved.

To facilitate completion of a fully connected physical map, research projects in the following areas are encouraged:

- o Development of methods for isolating large amounts of purified human chromosomes, chromosome segments, and restriction fragments for mapping and sequencing.
- o Development of cloning techniques that improve upon current approaches to constructing complete physical maps. The development of reproducible methods that: (1) ensure that cloned inserts are stable and are at least one megabase in size, (2) avoid artifacts, such as dimeric clones, and (3) ensure that cloned fragments derived from a single chromosomal location are particularly encouraged.
- o Construction of overlapping sets of cloned DNA, or closely spaced, unambiguously ordered DNA markers, with continuity over lengths of at least 2 million base pairs.
- o Assembly of STS maps of individual human chromosomes with the goal of having the STS markers spaced at approximately 100,000 base pair intervals.
- o Development of methods or strategies to solve the problem of closure.
- o Technology development to accelerate the completion of the physical map of the human genome.

Sequencing

The ultimate goal of the Human Genome Program is to determine the complete sequence of the human genome. To date, the largest genome that has been sequenced is a viral genome that is 240,000 base pairs in length. The human genome is 3 billion base pairs in length, four orders of magnitude larger. The current cost of DNA sequencing, in laboratories that do it routinely, is estimated to be between \$2-5 per base pair of finished sequence. If the entire human genome is to be sequenced, the cost of sequencing must be significantly reduced. Applications responding to this Program Announcement must address innovative approaches, including automation, that will increase the speed of sequencing megabases of DNA and significantly decrease the cost of DNA sequencing to \$0.50 or less per finished base pair within five years. Research projects are encouraged in the following areas:

- o Improvement of current technologies in order to reduce costs significantly below current costs;
- o Development of new methods, technologies, and strategies for large-scale sequencing including preparing and sequencing the DNA and assembling the data.

Only applications that aim to develop new or significantly improved current sequence technology should be submitted in response to this Program Announcement. Applications for routine sequencing will not be supported by the NCHGR. Applications to support feasibility studies for large-scale DNA sequencing using advanced state-of-the-art technology may be submitted only in response to a Request for Applications that is issued periodically in the NIH Guide for Grants and Contracts.

Informatics

The Human Genome Program will generate mapping and sequencing data from many laboratories, both national and international. While some computer tools and information systems for handling this type of data exist, none have been tested on a large scale to determine their capabilities to manage the voluminous amount and complexity of the data that will be generated. There is a need to develop appropriate computer tools and information systems for the collection, storage, retrieval, and distribution of mapping and sequencing data. In addition to the development of databases, it will be necessary to develop new methods and tools for the analysis and interpretation of genome maps and DNA sequences. Research projects are encouraged in the following general areas:

- o Development of effective software and database designs to support laboratory-based, large-scale mapping and DNA sequencing projects. Such projects should be undertaken in the context of actual mapping and sequencing efforts.
- o Creation of database and/or software tools that provide easy access to up-to-date physical and genetic mapping and DNA sequencing information and allow linkage of these specific data sets.
- o Development of analytical tools that can be used in the assembly and analysis of genomic data.
- o Technology development to accelerate the collection, storage, retrieval, analysis, and distribution of mapping and sequencing data.

APPLICATIONS PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). Applications will be accepted on the receipt dates for research grant applications (February 1, June 1, October 1). Application kits are available at most institutional business and grant/contract offices and may be obtained from the Division of Research Grants, National Institutes of Health, Westwood Building, Room 240, Bethesda, MD 20892, telephone 301/496-7441. The title and number of this announcement must be typed in Item 2 on the face page of the application.

The completed original application and five legible copies must be delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

REVIEW CONSIDERATIONS

Applications in response to this announcement will be reviewed in accordance with the usual NIH peer review procedures.

With the exception of program project (P01) applications, applications will be reviewed for scientific and technical merit by an appropriate study section in the Division of Research Grants. Program project applications will be evaluated by an appropriate review committee managed by an Institute or Center. Following the initial scientific review, applications will receive a second-level review by the National Advisory Council for Human Genome Research or another Council or Board.

Review Criteria

Review criteria that will be used to assess the scientific merit are:

- o Significance and originality of the research and methodological approaches;
- o Feasibility of the research and adequacy of the experimental design;
- o Training, experience, research competence, and commitment of the investigator(s);
- o Adequacy of the facilities and resources;
- o Appropriateness of the requested budget for the work proposed.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review;
- o Balance among research areas;
- o Availability of funds.



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For those applications assigned to the NCHGR, the following additional criteria will be used in making award decisions:

o Potential for developing technology or strategies for accelerating progress in mapping and sequencing the genomes of human and select model organisms;

o Value of the research for achieving the goals of the National Center for Human Genome Research;

o Adequacy of any plans proposed for managing data and sharing data and resources in a timely manner;

In addition, priority will be given to applications from U.S. institutions.

INQUIRIES

The program administrators and grants management officer welcome the opportunity to discuss the program interests of the NCHGR and PHS grants policy, respectively, with prospective applicants and current grantees and encourages telephone, electronic and written inquiries. For additional information, contact:

Genetic and Physical Mapping Grant Applications

Bettie J. Graham, Ph.D.
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Sequencing and Technology Development Grant Applications

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Informatics Applications

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PHS Grants Policy

Ms. Alice Thomas
Chief, Grants and Contracts Management Branch
National Center for Human Genome Research
Building 38A, Room 613
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Telephone: (301) 402-0733

AUTHORITY AND REGULATION

This program is described in the Catalog of Federal Domestic Assistance No. 93.172. Awards will be made under the authority of the Public Health Service Act, Section 301 (Public Law 78-410, as amended 42 U.S.C. 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to Health Systems Agency review.

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March 13, 1992

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P.T. 42; K.W. 0715035, 1014006

National Cancer Institute

The National Cancer Institute is sponsoring one-day preapplication conferences for three new cooperative agreements: the National Black Leadership Initiative on Cancer (NBLIC), the National Hispanic Leadership Initiative on Cancer (NHLIC), and the Appalachia Leadership Initiative on Cancer (ALIC). The conferences are open to anyone interested in applying for these cooperative agreements. Issues to be discussed include application procedures, program goals and objectives, and award criteria. Time will be allotted for questions and answers. The current schedule includes the following:

DATES: April 10, 1992, ALIC; April 13, 1992, NBLIC; April 13, 1992, NHLIC

CONFERENCE SITE: Bethesda, MD

REGISTRATION CONTACT:

Lois Schwartz
 National Outreach Initiatives Branch
 National Cancer Institute
 Executive Plaza South, Room 400-C
 Bethesda, MD 20892
 Telephone: (301) 496-8680

NOTICES OF AVAILABILITY (RFPs AND RFAs)

NON-HUMAN PRIMATE MODEL TO STUDY THE EFFECTS OF VACCINES IN PREGNANT FEMALES AND THEIR OFFSPRING

NIH GUIDE, Volume 21, Number 10, March 13, 1992

RFP AVAILABLE: NIH-NIAID-DMID-93-02

P.T. 34; K.W. 0755020, 0740075, 0775020, 0710070

National Institute of Allergy and Infectious Diseases

The Respiratory Diseases Branch, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, has a requirement to develop and characterize an animal model system with special emphasis on a primate model in which to study the effects of vaccination of pregnant females on their offspring. The long-term goal of the research is to gather evidence for the safety and efficacy of maternal immunization during pregnancy for the protection of the newborn by placentally transferred antibody against frequent infant pathogens. The purpose of this research effort will be to provide baseline information, using a primate model, on a minimum of three candidate vaccines for the maternal immunization approach over the five-year period of performance. The theory behind maternal immunization is that sufficient antibody directed against bacterial or viral antigens (e.g., type-specific capsular polysaccharides of GBS and Hib or purified surface proteins of RSV) can protect against systemic infection and that antibody elicited by vaccination of pregnant women could confer protection to their infants through placental transfer. Maternal immunization could, therefore, be viewed as an approach that might provide short-term passive immunity, obviating the need for neonatal immunization when it is less likely to be effective. Indeed, there is circumstantial evidence that placentally transferred natural maternal antibody can afford protection to the offspring against infection with group B Streptococcus types III, Ib, and Ia, Hib, E. coli K1, N. meningitidis groups A and C and RSV. Passive protection of newborns for the first few months of life would bring them into an age range in which subsequent vaccination could stimulate immunity more effectively.

The Request for Proposals NIH-NIAID-DMID-93-02 will be issued on or about March 24, 1992. Responses will be due by close of business June 24, 1992. It is anticipated that a completion-type contract will be awarded with incremental funding over a period of five years. Any responsible offeror may submit a proposal that will be considered by the Government. To receive a copy of this RFP, supply this office with two self-addressed mailing labels. Telephone inquiries will not be honored and all inquiries must be in writing and addressed to the office listed below:

Anthony J. Murray
Contracting Officer, Contract Management Branch
National Institute of Allergy and Infectious Diseases
The Solar Building, Room 3C07
6003 Executive Boulevard
Bethesda, MD 20892

This advertisement does not commit the Government to award a contract.

GENES RESPONSIBLE FOR INSULIN DEPENDENT DIABETES MELLITUS

NIH GUIDE, Volume 21, Number 10, March 13, 1992

RFA AVAILABLE: DK-92-14

P.T. 34; K.W. 1002019, 0715075, 0710030, 0760015

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: June 18, 1992

Application Receipt Date: July 22, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites investigator-initiated research grant applications to identify specific genes responsible for insulin dependent diabetes mellitus (IDDM) in humans. It is anticipated that this identification will require an interdisciplinary approach to develop and utilize strategies that will elucidate genes responsible for IDDM by using appropriate family pedigrees. This solicitation intends to support the efforts of several independent investigators, working in a collaborative manner to acquire sufficient genetic material, achieve the mutual objectives, and efficiently integrate and analyze the results obtained.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Genes Responsible for Insulin Dependent Diabetes Mellitus, is related to the priority area of diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications for research grants may be made by public and private, foreign and domestic, for-profit and non-profit organizations, such as universities, colleges, hospitals and laboratories, units of State and local governments, and authorized units of the Federal Government. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

The mechanism of support for this program will be the research project grant (R01). The regulations (CFR Title 42, Part 52 and, as applicable to State and local governments, Title 45, Part 74) and policies that govern the research grant programs of the National Institutes of Health will prevail. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed five years. The anticipated award date will be April 1, 1993.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary NIH peer review procedures.

FUNDS AVAILABLE

Up to \$1 million for first-year expenses, and additional approved expenses for up to five years, will be committed to fund applications submitted in response to this RFA. The NIDDK plans to make approximately five awards in FY 1993 contingent on the receipt of highly meritorious applications in response to this solicitation. In order to adhere to prudent principles of cost-containment, requested direct costs may not exceed \$160,000. The award of grants pursuant to this RFA is contingent on the availability of funds for this purpose.

RESEARCH OBJECTIVES

The objective of this RFA is to stimulate investigator-initiated research grant applications designed to develop and utilize new molecular genetic strategies to provide a better understanding of the major human genes involved in IDDM. To achieve this objective, appropriate family pedigrees may need to be collected as a prerequisite for the identification or the verification of specific gene involvement. It is anticipated that these results will elucidate mechanisms involved in disease onset, thus enabling the development of specific intervention therapies and the identification of individuals at risk for the development of IDDM. Relevant research topics listed below are examples and should not be construed as required or limiting. Applications responsive to this solicitation would include:

- o development of gene mapping strategies for the identification and localization of genes for IDDM
- o utilization of subtractive hybridization techniques to identify pathophysiologic processes in IDDM
- o employment of informative polymorphic markers, such as variable number repeat polymorphisms or microsatellite markers, to evaluate relevant family pedigrees

Applications must propose the testing of an hypothesis rather than the establishment of, for example, a genetic resource.

This RFA is designed to identify genes associated with IDDM; the NIDDK anticipates a future RFA specifically focusing on the identification of genes involved with non-insulin dependent diabetes mellitus.

SPECIAL REQUIREMENTS

Upon initiation of this program, the NIDDK will sponsor periodic meetings to encourage exchange of information among investigators, foster collaborative efforts between program grantees, and identify resources that would enhance the productivity of grantees. Applicants should include a statement in the application indicating a willingness to participate in such meetings and to cooperate with other researchers in the exchange of data, materials, and ideas. Funds to participate in these meetings should be included in the requested budget. In the case of a collaboration, inclusion of an agreement of participants to adhere to group decisions on data ownership and publication rights may be advantageous.

If several independent investigators have entered into a collaboration, it is necessary to identify a specific investigator who will act as the group coordinator. All applications submitted as components of a collaboration MUST cite the group coordinator on page 2 under "Key Personnel Engaged on Project" of the form PHS 398. Direct costs related to this coordinating activity may not exceed \$50,000 per year. These funds would be in addition to the funds (\$160,000) related to the research activities proposed by the coordinating institution.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Potential applicants are strongly encouraged to submit a letter of intent by June 18, 1992. The letter of intent is to include a descriptive title of the proposed research, the name, address, and telephone number of

the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the applications may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIDDK staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Robert D. Hammond, Ph.D.
Chief, Review Branch
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 605
5333 Westbard Avenue
Bethesda, MD 20892

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91), that is available from an applicant institution's Office of Sponsored Research and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 444, Bethesda, MD 20892, telephone (301) 496-7441. Applications must be received by July 22, 1992.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. In the event that the number of applications is large compared to the number of awards to be made, the NIH may conduct a preliminary scientific peer review to eliminate those applications that are clearly not competitive. Competitive applications will be assigned to a special peer review group by the NIDDK. Applications in response to this solicitation will be reviewed using the usual NIH peer review procedures.

INQUIRIES

It is essential that prospective applicants obtain the full text of this RFA prior to developing their applications. The RFA may be obtained from:

Joan T. Harmon, Ph.D.
Executive Director, Diabetes Research Program
Division of Diabetes, Endocrinology and Metabolic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 622
Bethesda, MD 20892
Telephone: (301) 496-7731
FAX: (301) 496-9721

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.847, Diabetes, Endocrinology and Metabolism Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

RESEARCH CENTERS ON ORAL HEALTH IN AGING

NIH GUIDE, Volume 21, Number 10, March 13, 1992

RFA AVAILABLE: DE-92-02

P.T. 34; K.W. 0715148, 0710010, 0710030, 0404000, 0785055

National Institute of Dental Research
National Institute on Aging

Letter of Intent Receipt Date: August 1, 1992
Application Receipt Date: November 10, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The National Institute of Dental Research (NIDR) and the National Institute on Aging (NIA), as part of their expanding programs of research on the oral health of older Americans, invite applications from United States institutions for the support of Research Centers on Oral Health in Aging (RCOHAs). The primary goal of these centers is to provide support for interrelated, multidisciplinary, basic biomedical and behavioral research and clinical or epidemiological studies of oral health in relation to aging.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Research Centers on Oral Health in Aging, is related to the priority area of oral health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Foreign organizations are not eligible to apply. However, domestic applications may include international components. Applications with key personnel, such as center directors or investigators, who are minority individuals and/or women are encouraged. Although an application must be submitted from a single institution, it may include consortia arrangements with other institutions. To be eligible for a center grant under this program, the potential applicant institution must have ongoing, independently supported research and must propose new research in the area of oral health in aging.

MECHANISM OF SUPPORT

RCOAs will be supported by specialized center grants (P50) for a period of five years, commencing as early as September 1, 1993. This RFA is a one-time solicitation. Subsequent support will be contingent upon program needs and an institution's ability to compete successfully in response to an RFA. In addition to support for multidisciplinary research projects, support will be provided for core resources the sharing of which will facilitate the total research effort. Each core unit must be utilized by at least two projects. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant.

FUNDS AVAILABLE

It is anticipated that one or two awards will be made and at least \$750,000 in total cost will be committed for the first year of support for the entire program, if a sufficient number of applications of high scientific merit are received. First year budgets may not exceed \$500,000 in direct costs. Although this program is provided for in the financial plans of the NIDR and the NIA, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The primary goal of the RCOHA program is to provide support for interrelated, multidisciplinary, basic biomedical and behavioral studies and clinical or epidemiological research in the broad area of oral health in relation to aging. The secondary goal is to create centers of excellence that will attract investigators of high quality to this field of endeavor, provide challenging opportunities for research training at all levels of career development, and serve as magnet organizations to foster productive research-related relationships with other institutions. Some examples of research areas to be addressed regarding oral health in the elderly are cited in the RFA.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by August 1, 1992, a letter of intent that includes a descriptive title for the RCOHA, each project and core, gives the name, address, and telephone number of the center director and the identities of other key personnel and participating institutions and departments, and identifies this RFA by number and title. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains is helpful in planning for the timely review of applications. It allows NIDR staff to estimate the potential review workload and to avoid possible conflict of interest in the review. The letter of intent is to be addressed to:

G.G. Roussos, Ph.D.
Director, Salivary Research and Oral Biology Centers Program
Extramural Program
National Institute of Dental Research
Westwood Building, Room 505
Bethesda, MD 20892
Telephone: (301) 496-7884

APPLICATION PROCEDURES

Applications are to be prepared on form PHS 398 (rev. 9/91), Application for PHS Grant, available at most institutional business or grants and contracts offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892 (telephone: 301-496-7441). Applications must be received by November 10, 1992. If an application is received after that date, it will be returned to the applicant. Detailed instructions on application submission are described in the RFA.

REVIEW CONSIDERATIONS

Applications will be evaluated for scientific and technical merit by a special review committee convened by the NIDR Scientific Review Office in consultation with the NIA. Prior to the initial review, a triage mechanism may be employed to determine competitiveness among the applications received. An applicant interview or site visit may be conducted. Non-competitive or non-responsive applications and those that exceed the budget limitation will be returned to the applicant. Secondary review will be conducted by the National Advisory Councils of the NIDR and the NIA. Factors to be considered in the evaluation of applications are discussed in detail in the RFA.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to Dr. G. G. Roussos at the address and telephone number listed under LETTER OF INTENT.

Direct inquiries regarding fiscal matters to:

Ms. Theresa Ringler
Chief, Grants Management Office
Extramural Program
National Institute of Dental Research
Westwood Building, Room 518
Bethesda, MD 20892
Telephone: (301) 496-7437

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.121. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NATIONAL BLACK LEADERSHIP INITIATIVE ON CANCER

NIH GUIDE, Volume 21, Number 10, March 13, 1992

RFA AVAILABLE: CA-92-10

P.T. 34, FC; K.W. 0715035, 0411005, 0745027, 0403004, 0795003

National Cancer Institute

Letter of Intent Receipt Date: April 10, 1992

Application Receipt Date: May 21, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The National Cancer Institute (NCI) through the Division of Cancer Prevention and Control (DCPC), Cancer Control Science Program (CCSP), National Outreach Initiatives Branch (NOIB), invites cooperative agreement applications from organizations to participate, with the assistance of the NCI in establishing a cancer prevention and control community outreach program. This project will involve planning, developing, and implementing cancer awareness activities with lay and professional Black Americans to reduce cancer incidence and mortality rates, increase survival rates, address risk behaviors, and improve screening use and early detection rates within the U.S. Black American community. The benefits that will accrue from implementation of the objectives of this RFA will also be applicable to other populations that reside within the specified geographical areas of the Black community.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objective of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, National Black Leadership Initiative on Cancer, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Print Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applicants may be domestic for-profit and non-profit organizations, public and private such as universities, colleges, hospitals, laboratories, units of State and local governments, health boards, public health departments, territorial health departments (including the District of Columbia), volunteer organizations, clinics, coalitions, and consortia. Women and minority investigators are encouraged to apply. Teams of applicants are encouraged. Among a team of applicants, one must be designated as the lead applicant and assume

responsibility for the conduct of the project.

Foreign organizations are not eligible to apply, and applications from domestic organizations may not include international components.

MECHANISM OF SUPPORT

Support of this program will be through the cooperative agreement (U01), an assistance mechanism in which substantial NIH programmatic involvement with the recipient during performance of the planned activity is anticipated. The nature of NCI staff involvement is described in the "Terms of Cooperation" Section. The award will be administered in accordance with PHS grants policy as stated in the Public Health Service Grants Policy Statement.

This RFA is a one-time solicitation. Future competitive continuation applications will compete with all investigator-initiated applications and be reviewed by the Division of Research Grants. If the NCI determines that there is a sufficient continuing program need, the NCI may invite the awardee to submit a continuation application for review according to the procedure described in the Review Considerations section. The total award period for applications submitted in response to the present RFA may not exceed five years.

FUNDS AVAILABLE

Approximately \$1 million in total costs per year for five years will be committed to fund one award. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of a cooperative agreement pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

There are substantial data that show that Black Americans have higher overall incidence and mortality rates than do whites for all but 3 of 25 primary cancer sites. Even for certain types of cancers that occur less frequently in Black Americans, i.e., cancers of the bladder and corpus uteri, Black Americans have poorer survival rates than whites. Fewer Black Americans have adequate health insurance coverage, thereby decreasing the likelihood of access to early detection methods and state-of-the-art treatment.

Because cancer prevention and control programs/activities are generally confronted with culturally based traditions and enormous individual resistance within minority populations, it is essential that such impediments be addressed by empowering the Black American community to act on its own behalf through facilitators who understand and are sensitive to Black American cultural traditions.

This RFA will support activities involving the efficacy of existing cancer prevention and control intervention strategies within the Black American population. Results from the evaluation of these activities are expected to influence the development and implementation of new NCI cancer prevention and control interventions that are specific and culturally sensitive for the U.S. Black American population.

It is envisioned that the project will operate in several well-defined geographical regions of the U.S. and will involve three overlapping phases: Planning and Development (Phase I), Program Implementation and Evaluation (Phase II), and Data Analysis and Reporting (Phase III).

STUDY POPULATIONS

The project is National in scope and specifically targets the approximately 30 million Black American males and females of all age groups who comprise approximately 12 percent of the U.S. population. Applicants must demonstrate the ability to access Black American communities and recruit volunteer workers to lead and/or support cancer intervention activities.

Due to the nature of this solicitation, the inclusion of minorities as a requirement is satisfied.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 10, 1992, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NCI staff to estimate the potential review workload and to avoid possible conflicts of interest in the review.

The letter of intent is to be sent to:

Veronica Y. Brown
NBLIC Program Director
National Outreach Initiatives Branch
National Cancer Institute
Executive Plaza South, Room 400C
Bethesda, MD 20893-4200
Telephone: (301) 496-8680

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for the cooperative agreement under this RFA. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/496-7441; and from the NCI Program Director named below. Applications must be received by May 21, 1992. If an application is received after that date, it will be returned to the applicant.

REVIEW CONSIDERATIONS

All applicants must clearly define the geographic area within the United States where they will target program efforts. Applicants are encouraged to submit and describe their own ideas on how best to meet the goals of this announcement and to identify in-kind contributions and/or co-sponsors for specific personnel, activities, and facilities. Applications will be judged primarily on evidence of an understanding of the Black American community and its cancer control needs; the ability to access and obtain community participation, to identify and recruit lay and professional leaders, to establish community coalitions, and to collaborate with Black operated health care and other organizations; discussion of considerations relevant to the RFA; qualifications of the investigators including community outreach experience, Black American cultural competence, and cancer control and communications expertise; capability to perform the work proposed; and a demonstrated willingness to work together with other awardees funded under this cooperative agreement and the NCI Program Director.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify issues or questions from potential applicants are welcome.

Direct inquiries regarding programmatic issues to:

Veronica Y. Brown
NBLIC Program Director
National Outreach Initiatives Branch
National Cancer Institute
Executive Plaza South, Room 400C
Bethesda, MD 20892-4200
Telephone: (301) 496-8680

Direct inquiries regarding fiscal matters to:

Eileen Natoli, Team Leader
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
6120 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7800 Ext. 56

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NATIONAL HISPANIC LEADERSHIP INITIATIVE ON CANCER

NIH GUIDE, Volume 21, Number 10, March 13, 1992

RFA AVAILABLE: CA-92-09

P.T. 34, FD; K.W. 0715035, 0411005, 0745027, 0403004, 0795003

National Cancer Institute

Letter of Intent Receipt Date: April 10, 1992

Application Receipt Date: May 21, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAME IN INQUIRIES, BELOW.

PURPOSE

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites cooperative agreement applications from organizational entities to participate, with the assistance of the NCI, in establishing a culturally credible national community outreach cancer prevention and control program for U.S. Hispanic Americans. The program will advance through stages of planning, development, implementation and evaluation and consist of cancer awareness activities aimed at reducing cancer incidence and mortality rates in targeted Hispanic Subgroups. The benefits that will accrue from implementation of the objectives of this RFA will also be applicable to other populations that reside within the specified geographical areas of the

Hispanic American community. The range of outreach activities should be multifaceted and include, for example:

- o Mobilization of national, state, and local Hispanic lay and professional leaders to address cancer issues among Hispanics.
- o Building of coalitions between and among established Hispanic health and community organizations, universities with significant Hispanic student enrollments and faculty, private and public cancer care and research projects.
- o Addressing the various cancer risk behaviors and cancer screening practices of specific Hispanic subgroups and instituting activities to promote change for improved cancer incidence, mortality and early detection rates among Hispanics.
- o Evaluation of the efficacy and effectiveness of outreach activities at the national and regional levels.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, National Hispanic Leadership Initiative on Cancer, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations that have a substantial number of Hispanic staff and clients, either public or private, such as universities, Hispanic organizations, coalitions of health professionals, or combinations thereof. Teams of applicants are eligible.

MECHANISM OF SUPPORT

Support for this program will be through a cooperative agreement (U01). The cooperative agreement is an assistance mechanism in which NCI programmatic involvement with the recipient during the performance of the planned activity is anticipated. Applicants will be responsible for the planning, direction, and execution of the proposed project.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete as research project applications with all other investigator-initiated applications and be reviewed according to the customary NIH peer review procedure.

FUNDS AVAILABLE

Approximately \$1 million in total costs per year for five years will be committed to specifically fund one award under this RFA. This funding level is dependent on the receipt of a sufficient number of applications of high programmatic merit. The total project period for awards under this RFA may not exceed five years. The earliest feasible start date for the initial award will be September 1, 1992.

RESEARCH OBJECTIVES

The National Hispanic Leadership Initiative on Cancer (NHLIC) long-term program goals are to: (a) improve cancer survival rates and reduce cancer mortality rates in Hispanic communities; (b) prevent future cancer incidence and mortality rate increases in Hispanic communities; and (c) address the barriers preventing Hispanics from gaining access to quality health care and referral to appropriate screening, diagnostic, and therapeutic cancer programs.

The specific objectives proposed under this RFA are to: (a) develop a national outreach program to promote and increase cancer prevention and control activities in Hispanic communities; (b) access major Hispanic subgroups and key community Hispanic lay and professional leaders to organize and mobilize regional and local outreach activities; (c) develop coalitions with health, religious, social, medical, academic, and media groups and the specific Hispanic population that they serve; (d) evaluate the efficacy and effectiveness of the outreach strategies, approaches, methods used, and outcome measures, and (e) measure impact at the national, regional, and local levels.

STUDY POPULATION

The targeted population is the approximately 22 million U.S. Hispanic Americans, males and females of all ages and economic status, which includes: Mexican Americans, Puerto Ricans, Cuban Americans, Central and South Americans, and other Hispanic groups. Applicants responding to this RFA are expected to access major Hispanic groups to significantly increase cancer awareness and decrease cancer risk behaviors in these populations.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

Due to the nature of this solicitation, the inclusion of minorities as a requirement is satisfied.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 10, 1992, a letter of intent that includes a descriptive title of the proposed outreach program, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in

response to which the application may be submitted. Although not required or binding, the letter of intent allows NCI staff to estimate potential review workload and to avoid possible conflict of interest in the review. The letter of intent may be sent to the NCI program staff identified in the INQUIRIES section.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for this cooperative agreement. These forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone: 301/496-7441.

Applications must be received by May 21, 1992.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the Division of Research Grants for completeness. Evaluation for responsiveness to program requirements and criteria stated in the RFA is an NCI program staff function. Applications that are judged non-responsive will be returned to the applicant. Those applications that are competitive and responsive will be evaluated for technical merit by an appropriate peer review group convened by the NCI. The second level of review will be provided by the National Cancer Advisory Board. Questions concerning responsiveness to the RFA may be directed to the NCI program staff identified in the INQUIRIES section. Review criteria that apply include:

- o Substantiation of programmatic, technical, and health significance.
- o Appropriateness and adequacy of the strategies and procedures proposed to carry out the outreach program.
- o Qualifications, training, and bilingual/bicultural competency of the Principal Investigator (National Coordinator), Regional Coordinators and other key project staff.
- o Appropriateness of proposed budget and duration in relation to the proposed initiative including proposed regional budgets.

INQUIRIES

Direct inquiries regarding programmatic issues to:

NHLIC Program Director
National Outreach Initiatives Branch
Division of Cancer Prevention and Control
National Cancer Institute
Executive Plaza South, Room 400C
9000 Rockville Pike
Bethesda, MD 20892-4200
Telephone: (301) 496-8680

Direct inquiries regarding fiscal matters to:

Eileen Natoli, Team Leader
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
9000 Rockville Pike
Bethesda, MD 20892-4200
Telephone: (301) 496-7800 Ext. 56

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399, Cancer Control Science Program. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A. (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

APPALACHIA LEADERSHIP INITIATIVE ON CANCER

NIH GUIDE, Volume 21, Number 10, March 13, 1992

RFA AVAILABLE: CA-92-11

P.T. 34, BB; K.W. 0715035, 0411005, 0745027, 0403004, 0795003

National Cancer Institute

Letter of Intent Receipt Date: April 10, 1992
Application Receipt Date: May 21, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The National Outreach Initiatives Branch (NOIB), Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites cooperative agreement applications from organizations to participate in establishing a strong, cancer control outreach program in Appalachia. For purposes of this RFA, Appalachia is defined according to the Appalachian Regional Commission's current definition that includes all of West Virginia and parts of 12 other states: Alabama, Georgia, Kentucky, Maryland, Mississippi, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, and Virginia. The long-term goals of the program are to achieve reductions in cancer incidence and mortality, increases in cancer survival, and increases in the diagnosis of cancers at earlier stages within the population of the Appalachian region. This RFA invites applications that propose mobilization of community lay and professional leaders to develop and support community cancer control coalitions throughout Appalachia. These coalitions will design and implement long-range, comprehensive, multi-disciplinary, and community-wide cancer control outreach projects and stimulate greater cancer control data collection and research efforts. As a result, measurable improvements would be expected in knowledge about prevention and early detection of cancer and access and utilization of diagnostic and treatment services for cancer.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objective of "Healthy People 2000," a PHS-led national activity for getting priority areas. This RFA, Appalachia Leadership Initiative on Cancer, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by public and private, for-profit and non-profit, organizations serving a substantial number of Appalachian clients such as universities, public health departments, voluntary organizations, research centers, hospitals, consortia of health providers, units of State and local governments, and eligible agencies of the Federal Government. Teams of applicants are encouraged. Note that awards will not be made to foreign institutions and that applications from domestic organizations may not include international components.

MECHANISM OF SUPPORT

Support for this program will be through the cooperative agreement (U01). The cooperative agreement is an assistance mechanism in which substantial NCI programmatic involvement with the recipients during performance of the planned activity is anticipated. There are special requirements with the cooperative agreement mechanism for awardee and Federal staff authorities, responsibilities, and functions. Applicants will be responsible for the planning, direction, and execution of the proposed project. The total project period for applications submitted in response to the present RFA may not exceed five years.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete as research project applications with all other investigator-initiated applications and be reviewed according to the customary NIH peer review procedures.

FUNDS AVAILABLE

Approximately \$1 million in total costs per year for five years will be committed to fund applications that are submitted in response to this RFA. It is anticipated that up to four awards will be made. The total project period of these awards may not exceed five years. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of a cooperative agreement pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

This cooperative agreement is intended to improve cancer prevention and control in Appalachia through the formation of community coalitions to design, implement, and support comprehensive cancer control outreach activities. These coalitions will promote systems change in communities and facilitate the development, implementation, maintenance, and evaluation of long-range, comprehensive, multi-disciplinary, and community-wide projects.

The long-term goals of this cooperative agreement are to: (1) reduce cancer incidence and mortality and improve cancer survival rates in Appalachia; (2) prevent future cancer incidence and mortality rate increases; (3) reduce the barriers preventing Appalachians from gaining access to quality cancer control services and referral to appropriate screening, diagnostic, and therapeutic cancer programs; and (4) stimulate greater participation of Appalachians in community cancer control outreach programs.

The specific objectives are to: (1) create a network of cancer control community coalitions throughout Appalachia; (2) develop, disseminate, and support effective cancer control intervention programs and strategies in Appalachian communities; (3) mobilize community lay and professional leaders to develop and support cancer control community coalitions and outreach activities; (4) stimulate cancer control data collection and research efforts in Appalachia; and (5) evaluate the effectiveness of this initiative.

STUDY POPULATIONS

The targeted population intended under this RFA is the approximately 21 million Americans living in the

Appalachian region, as defined by the Appalachian Regional Commission. Applicants responding to this RFA are expected to successfully access a significant portion of this population and thereby decrease cancer incidence and mortality, increase cancer survival, and increase the diagnosis of cancers at earlier stages.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 10, 1992 a letter of intent that includes a descriptive title of the proposed research; the name, address, and telephone number of the Principal Investigator; the identities of other key personnel and participating institutions; and the number and title of the RFA in response to which the application is being submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent application, the information that it contains is helpful in planning for the review of applications. It allows NCI staff to estimate the potential review workload and to avoid possible conflict of interest in the review. The letter of intent is to be sent to:

Nancy K. Simpson, Sc.M.
ALIC Program Director
National Outreach Initiatives Branch
National Cancer Institute
Executive Plaza South, Room 400-C
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-8680

APPLICATION PROCEDURES

Applications are to be submitted on the 9/91 revised grant application form PHS 398. These forms are available at most institutional business offices and the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/496-7441. Applications must be received by May 21, 1992. All applicants must clearly define the geographic area within Appalachia where they will target program efforts.

REVIEW CONSIDERATIONS

Applications will be judged primarily on evidence of an understanding of the Appalachian region and its cancer control needs; the ability to access and obtain participation of Appalachian communities, to identify and recruit formal and informal leaders, to establish community coalitions, and to collaborate with Appalachian health care and other organizations; discussion of considerations relevant to the RFA; qualifications of the investigators, including community outreach experience, Appalachian cultural competence, and cancer control and communications expertise; capability to perform the work proposed; and a demonstrated willingness to work together with other awardees funded under these cooperative agreements and the NCI ALIC Program Director.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA and inquiries regarding programmatic issues to:

Nancy K. Simpson, Sc.M.
ALIC Program Director, National Outreach Initiatives Branch
National Cancer Institute
Executive Plaza South, Room 400-C
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-8680

Direct inquiries regarding fiscal issues to:

Eileen Natoli, Team Leader
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-7800 Ext. 56

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MENTAL RETARDATION RESEARCH CENTERS - RECOMPETITION

NIH GUIDE, Volume 21, Number 10, March 13, 1992

RFA AVAILABLE: HD-93-01

P.T. 04; K.W. 0715130, 0745020, 0745027, 0404000, 0404004, 0710030

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: April 17, 1992

Application Receipt Date: July 17, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The National Institute of Child Health and Human Development (NICHD), through the Mental Retardation and Developmental Disabilities (MRDD) Branch, Center for Research for Mothers and Children (CRMC), invites research center core grant applications (P30) to develop new knowledge in the field of prevention, treatment, and amelioration of mental retardation and developmental disabilities. Four centers may be supported in response to this announcement.

The primary objective of the NICHD Mental Retardation Research Centers (MRRCs) is to provide support and facilities for a cohesive, interdisciplinary program of research and research training in mental retardation and related aspects of human development.

NICHD has supported MRRCs through the provision of core grants (P30) which facilitate program coordination and support central research core facilities. Funds for the research projects using these core units come from independent sources including Federal, State and private organizations. This announcement seeks applications from existing MRRCs and from other institutions that have a comparable concentration of research in mental retardation.

A major goal of the MRDD Branch's research program is to prevent and/or ameliorate mental retardation. In general, the degree of impairment associated with mental retardation varies in relation to the cause. Moderate and more severe mental retardation often results from problems that produce profound alterations in brain development and/or function. Diminished intellectual and adaptive capacity can often be traced to defective genes, teratogenic agents, infections, nutritional deficits, accidents, diseases and other disorders causing brain damage. A larger proportion of cases of mental retardation is related to environmental conditions and disorders of unknown etiology. These complex problems require integrated multidisciplinary approaches involving biomedical and behavioral sciences in a variety of settings.

The purpose of a Mental Retardation Research Center is to provide a research environment that facilitates interdisciplinary collaboration among investigators who are working in areas of relevance to the prevention and amelioration of mental retardation. Such research will cover a broad spectrum of scientific approaches ranging from laboratory research on fundamental processes of abnormal development to clinical and educational research in which persons with mental retardation are studied.

It is thought that major solutions to the problems of mental retardation may be found as a result of multidisciplinary collaboration involving a variety of approaches in the MRRCs. As a result of the administrative and scientific organization within a MRRC and across the network of MRRCs, opportunities for breakthroughs will be enhanced.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Mental Retardation Research Centers, is related to several priority areas including nutrition, alcohol and other drugs, mental health and mental disorders, environmental health, maternal and fetal health, HIV infection, immunization, and infectious diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-011-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, and units of State and local governments. As stated in the NICHD Center Guidelines, the NICHD will not support more than one center grant (P30, P50) in a given department or specialty unit.

MECHANISM OF SUPPORT

Mental Retardation Research Center grants will be supported through the customary grant-in-aid mechanism. The application should be prepared in a manner consistent with the general guidelines presented in the publication titled P30 CENTER CORE GRANT GUIDELINES which are available from the NICHD office listed below.

Awards will be made for a period of five years. To be eligible for award as an MRRC, the Center must provide core support for a minimum of 10 projects funded from non-university sources.

The total direct costs requested for the first year of a new Center Core Grant (P30) should not exceed \$500,000. Renewal applications from existing P30 Centers should not request initial year direct costs exceeding 120 percent of the Notice of Grant Award level of direct costs for the final year of the preceding project period, or \$500,000 direct cost, whichever is greater. Budgets of applications for new and renewal support will be stringently reviewed within these guidelines. Applications with budget requests exceeding these guidelines will be returned to the applicant without review.

FUNDS AVAILABLE

This is the fifth in a series of annual announcements. Plans are to make four awards in fiscal year 1993. The estimated funds available for the first year of support for the entire program are \$3.1 million total costs.

This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the Institute, awards pursuant to this RFA are also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

MRRC Core Grants are intended to bring together in a center a variety of disciplines to work on the common problems of mental retardation. Consequently, applications for Mental Retardation Center Core Grants (P30) should include investigators studying a range of topics in basic and clinical or applied research. Applicants are encouraged, but are not required, to include both biomedical and behavioral components from among the following topics:

1. Developmental neurobiological studies relevant to MRDD.
2. Inborn errors of metabolism relevant to MRDD.
3. Genetic/cytogenetic disorders associated with MRDD.
4. Molecular biology; development of animal models.
5. Toxicology and physical environmental factors in the etiology, treatment and prevention of MRDD.
6. Intellectual, behavioral, physical and the intergenerational effects of malnutrition.
7. Developmental pharmacology and psychopharmacology.
8. Infectious diseases in the etiology, prevention and treatment of MRDD.
9. Diagnosis; identification of children and infants at risk for MRDD.
10. Perinatal problems associated with MRDD.
11. Psychobiological processes in MRDD.
12. Psychological processes in MRDD.
13. Early intervention for infants at risk to develop MRDD.
14. Behavioral analysis of individuals with MRDD.
15. Family and community studies.
16. Language and communication studies.
17. Learning disabilities, dyslexia, and attention deficit disorder.
18. Behavior in residential and educational settings.
19. Socioeconomic status, ethnicity, and ecological processes.
20. Epidemiology of MRDD.

STUDY POPULATIONS: SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

If an investigator is satisfied that his/her institution meets the qualifications prescribed and elects to apply for a Mental Retardation Research Center grant (P30), a letter of intent should be submitted to the MRDD Branch at the address given below by April 17, 1992. The letter of intent should include a descriptive title, the name, address, and telephone number of the principal investigator, the names of other key personnel and participating institutions, the core unit directors and principal investigators of the research projects that would use the core units, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows Institute staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

MRDD Branch, CRMC
National Institute of Child Health and Human Development
Room 631, Executive Plaza North
6130 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-1383

APPLICATION PROCEDURES

The applicant is to submit the application using PHS 398 (rev. 9/91). Application kits containing this form and the necessary instructions are available in most institutional business offices or may be obtained from the

Office of Grant Inquiries, Division of Research Grants, NIH. The NICHD recommends that the application be developed in consultation with the MRDD Program staff, CRMC, who will provide whatever guidance is possible and appropriate in relation to both scientific and administrative issues. The completed application must be submitted to the Division of Research Grants on or before July 17, 1992.

REVIEW CONSIDERATIONS

Applications received in response to this RFA will be reviewed with each other on a nationwide competitive basis. The initial review for scientific merit will be carried out by the NICHD Mental Retardation Research Committee (MRRC) at its March 1993 meeting. Because a site visit is not a prerequisite for MRRC consideration, each application should be thorough and complete enough to stand on its own. The second-level review will be made by the National Advisory Child Health and Human Development Council at its June, 1993 meeting. The earliest possible funding will be August 1993.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Felix F. de la Cruz, M.D., M.P.H.
Chief, MRDD Branch, CRMC
National Institute of Child Health and Human Development
Executive Plaza North, Room 631
6130 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-1383

Direct inquiries regarding fiscal matters to:

Mr. Edgar D. Shawver
Supervisory Grants Management Specialist
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 505
6130 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-1303

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.865 Research for Mothers and Children. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

EFFECTIVE DISSEMINATION OF HEALTH AND CLINICAL INFORMATION AND RESEARCH FINDINGS

NIH GUIDE, Volume 21, Number 10, March 13, 1992

PA NUMBER: PA-92-51

P.T. 16; K.W. 1004017, 0730050, 1016002, 1016003

Agency for Health Care Policy and Research

PURPOSE

The Agency for Health Care Policy and Research (AHCPR) invites applications to conduct applied research and demonstrations on effective dissemination of health-related information and clinical practice guidelines, technology assessments, general health services research findings, and research findings used in policy decisions and recommendations.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Effective Dissemination of Health and Clinical Information and Research Findings, could be related to any priority area. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by public and private non-profit institutions, units of State and local government, and individuals. For-profit institutions are not eligible for AHCPR grants.

MECHANISM OF SUPPORT

This Program Announcement will use the traditional research grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. It is anticipated that projects will vary from one to three years in length. Project lengths could be up to five years in rare cases due to the complexity or breadth of the subject area, or in areas proposing to investigate the longer term effects of particular forms of dissemination.

RESEARCH OBJECTIVES

Background

The purpose of the AHCPR is to enhance the quality, appropriateness, and effectiveness of health care services and to improve access to that care. AHCPR is the Federal Government's focal point for general health services research, including medical effectiveness research, and has lead responsibility for the Medical Treatment Effectiveness Program (MEDTEP). MEDTEP projects systematically study the relationships between medical treatments and procedures and the outcomes. Patient Outcomes Research Team (PORT) projects focus on variations in clinical practice and outcomes for a particular medical condition. The AHCPR convenes expert non-Federal panels and awards contracts to develop clinical practice guidelines for specific conditions and treatments. The AHCPR Office of Technology Assessment evaluates medical devices, procedures and services and makes coverage recommendations to Federal health programs. The AHCPR intramural research program undertakes health policy research and analysis on National medical expenditures, hospital cost and utilization data, and long-term care. Health services research focuses on a broad range of policy and delivery system issues in the areas of cost and financing, primary care, and technology and quality assessment. In addition, the AHCPR is responsible for increasing the quality and quantity of data for general health services research, including medical effectiveness research.

The AHCPR authorizing legislation (the Omnibus Budget Reconciliation Act of 1989, P.L. 101-239) requires the AHCPR to disseminate as broadly as possible the products and results of its research. This Program Announcement for demonstrations and applied research is part of the AHCPR dissemination program. The focus on "effective dissemination" is based upon a growing recognition that distribution of information does not guarantee adoption or use. The definition of effective dissemination used in this PA goes beyond the traditional concepts of diffusion and distribution of information and encompasses the process through which target groups become aware of, receive, accept, and utilize disseminated information. The test of effective use is the extent to which target audiences become more informed, make decisions, or change behavior patterns as a result of using the disseminated information. The goal of effective dissemination is to improve patient care, patient outcomes and quality of life.

Early studies of innovation diffusion in the health arena examined the spread of new information, knowledge or technologies, the characteristics of the diffusion process, and the role that people and organizations played in the adoption of innovations. These studies confirmed that some innovations were not adopted or utilized and that there was a long lag time between availability and widespread use of new scientific information.

Underlying many efforts to provide new clinical information or practice guidelines to practitioners has been the assumption that clinical practice behavior will change if relevant scientific evidence is effectively disseminated to health care providers and patients. The dissemination-related health literature has focused primarily on the introduction of medical technology, the flow of new information into practice, continuing medical education, and more recently on physician behavior change resulting from the diffusion of new information or clinical practice guidelines. Most of this literature has focused on practitioners and health care settings. Pertinent research related to consumers has focused on public health and health education information, the psychology of mass communications and other work related to marketing. Research directed at policy makers has examined the use of data and evaluation studies in legislative and executive settings.

Objectives

The objective of this Program Announcement is to stimulate new grant applications for demonstrations and applied research projects that examine the most effective means of disseminating a broad range of products (health and clinical information, research findings, clinical practice guidelines, technology assessments, policy recommendations) to a wide variety of target groups (consumers, health care practitioners, the health care industry, researchers, policy makers, and the press). Applied research in effective dissemination should be multi-disciplinary, drawing on the fields of communications and information theory, commercial marketing, social and behavioral psychology, education, computer sciences, and policy sciences. The eventual goal is for disseminated information to be assimilated and used in ways that improve the effectiveness and quality of health care services, utilization of and access to those services, and ultimately patient outcomes and quality of life.

A. Audiences, media, and products of dissemination -- The audiences, media, and products of dissemination that are of interest to the AHCPR include:

Audiences: Consumers (individuals or organizations); health care practitioners of all disciplines (physicians, nurses, allied health professionals, and professional organizations); the health care industry (organizations, group practices and managed care organizations, third-party payers, medical equipment manufacturers, pharmaceutical manufacturers, Federal health care systems, quality assurance and utilization review organizations); policy makers (Federal, State and local, executive and legislative, and private sector decision makers); researchers (both biomedical and general health services); and the press (popular media and newspapers, general health, trade and scientific journals).

Media: Printed (direct mail, technical and trade journals, popular magazines and newspapers); and electronic (TV, radio, and electronic databases).

Products: General health services research findings; clinical information; clinical practice guidelines; health

technology assessments; research-based policy recommendations; and general health information for consumers.

B. Types of projects supported -- The AHCPR invites applications on effective dissemination that focus on practical methods to achieve better informed audiences, improved decision making, and behavioral change that improve the delivery of health care and patient outcomes. AHCPR encourages projects that involve dissemination of AHCPR products or other research and information products similar to AHCPR products so that findings can contribute to improving the effectiveness of the dissemination program. The following types of projects will be considered responsive to this Program Announcement:

1. Demonstration projects (with appropriate research hypotheses) measuring the effectiveness of dissemination mechanisms (e.g., continuing professional education, opinion leaders, peer review and feedback, computerized systems, incentives, organizational approaches) or combinations of mechanisms in stimulating the use of disseminated information;
2. Studies examining the comparative effectiveness of different dissemination mechanisms using the same information with different audiences or different information with the same audiences;
3. Studies examining the effectiveness of different dissemination mechanisms under conditions in which the target audiences are either economically advantaged or economically disadvantaged by the behavioral change;
4. Studies examining the comparative cost of different methods of stimulating behavior change (e.g., cost measures may be calculated by cost per thousand population, magnitude of changes);
5. Longitudinal studies of sustained change in knowledge, skills, attitudes, and behavior as a result of dissemination of health and clinical information;
6. Projects designed either to improve health services research methods as applied to effective dissemination or to overcome dissemination research problems, especially projects that focus on multi-disciplinary research methods (e.g., the use of behavioral change models in health information dissemination campaigns); and
7. Innovative research on unique methods of reaching particular audiences (e.g., informing consumers to stimulate and effect practitioner behavioral change and multi-faceted dissemination campaigns).

C. Research Questions -- The following questions are illustrative of the kinds of research questions that grant applications might address concerning the audiences, products, and dissemination mechanisms discussed above:

- o What can be learned from dissemination experiences of the past to help ensure that disseminated information is assimilated and used by target audiences? What are the crucial variables in these experiences (e.g., quality of information, format, endorsements, economic impact, targeting activities)?
- o How can the experience and knowledge of the commercial marketing and advertising enterprises be adapted to the dissemination of health and clinical information in the professional/patient environment to effect behavior change?
- o How effective are the mass media in transmitting health information to practitioners and consumers? What are the determinants of behavioral change resulting from information presented in the media?
- o What are the needs and preferred sources of different audiences for health and clinical information and how do these needs affect the design of dissemination strategies? What do we know about the needs of the six major groups of audiences and how do the needs differ? How do differences among audiences affect the development of dissemination strategies?
- o How do the attributes of disseminated products and information (credibility of source, content tailored to audience need, product format, timeliness, utility of product, adaptability, validity, ability to be evaluated) affect dissemination strategies and how are these attributes associated with acceptance and use or rejection of disseminated information?
- o When is the best moment in time for dissemination to take place to maximize the likelihood that it is used by a targeted audience? Does this moment differ across audiences?
- o Is the health belief model for disseminating health information to consumers the most appropriate one to guide dissemination strategies? What alternative models could be developed or considered?
- o What are the economic, social, educational, and psychological determinants of consumer and practitioner behavior in accessing and using health and clinical information? At what points in that behavior can dissemination strategies most effectively intervene to stimulate change in that behavior?
- o How do cultural, socioeconomic, and access factors affect the assimilation of clinical information by providers and patients within special populations or target groups and geographic areas (e.g., minority and rural)?
- o Who are health practitioner peers and what is the typology for their constituent groups? What are the determinants of change produced by peer influence?
- o How can the principles of "academic detailing" be adapted to dissemination strategies for consumers and policy makers?
- o What factors are associated with effective use of the professional education and continuing professional education systems in disseminating new scientific information and its adoption into clinical practice?

- o What roles do organizational and/or personal networks play in the dissemination process? Do networks speed the dissemination or the assimilation and use of new information? What are the implications for dissemination of the communication patterns within and between networks?
- o How can communication and computer technologies be designed to affect assimilation and retention by health care providers?
- o What is the comparative effectiveness of different systems to computerize medical practice guidelines in disseminating new clinical information to practitioners?
- o What is the effect of structural and process variables (e.g., multifaceted organizational relationships within provider organizations; work environment; personnel mix; administrative governance; medical direction; type of medical equipment available within an institution; degree of compliance with recommended guidelines; and level of internal communication) within different provider settings on the relationship between the assimilation of practice guidelines by providers and patient outcomes? How do these variables facilitate or hinder the dissemination and assimilation of new information and knowledge?
- o How do organizational factors affect the adoption of new information and innovations and when does that adoption result in decisions that improve efficiency or patient outcomes? Do different kinds of health care organizations or personnel within them (e.g., different management levels) differ in patterns of assimilation and use of information?
- o What is the appropriate typology for the use of new knowledge or new information by policy makers?
- o What is the most effective means of translating, synthesizing, or adapting data and findings from health services research and clinical trials into useful information for policy makers and decision makers at the Federal, State and local levels and the private sector?
- o How do economic and regulatory incentives affect the timing and nature of decisions to adopt and utilize medical practice guidelines?
- o What are the most effective avenues for reaching third party payers and other decision makers in the private sector with health and clinical information and research findings? What formats and products are associated with the most utility to these audiences?
- o How can dissemination strategies be made most cost-effective? When resources are insufficient to disseminate information broadly to all audiences, what mechanisms exist to select target groups and maximize the effectiveness of what is disseminated?

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS CONCERNING INCLUSION OF WOMEN AND MINORITIES IN RESEARCH STUDY POPULATIONS

The AHCPR requires all applicants for research grants to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study. Special emphasis must be placed on the need to include minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in research, a clear and compelling rationale should be provided. AHCPR will not award grants for applications which do not comply. If the required information is not contained in the application, the application will be returned without review.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, AHCPR recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans, Asian/Pacific Islanders, Blacks, Hispanics). Where appropriate, the applicant must provide the rationale for studies on single minority population groups.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific

question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit. State and local governments may use Form PHS 5161 and submit an original and two copies of the application.

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, MD 20892, telephone 301/496-7441. They may also be obtained from the Office of Scientific Review, Agency for Health Care Policy and Research, Suite 602, 2101 East Jefferson Street, Rockville, MD 20852, telephone 301/227-8449. The title and number of the Program Announcement must be typed in Section 2a on the face page of the application.

The completed original application and five legible copies (two copies when using the PHS 5161) must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892

The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

Applications must be received by the Division of Research Grants, NIH. The first due date is June 1, 1992. Thereafter, the due dates for application are October 1 and February 1 and June 1. However, an application received after a deadline may be acceptable if it carries a legible proof-of-mailing date assigned by the carrier and the proof-of-mailing date is not later than one week prior to the deadline date. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following work day. The receipt date will be waived only in extenuating circumstances. To request such a waiver, an explanatory letter must be included with the application. No waiver will be granted prior to receipt of the application.

REVIEW CONSIDERATIONS

The review criteria for these applications are the considerations of scientific and technical excellence, which include: adequacy of the method to carry out the project; availability of the data or the proposed plan to collect the data required for the project; qualifications and experience of the Principal Investigator and proposed staff; adequacy of the plan for organizing and carrying out the project; reasonableness of the proposed budget; and adequacy of the facilities and resources available to the applicant.

Upon receipt, applications will be reviewed for completeness. Incomplete applications will be returned to the applicant without further consideration. Applications will be evaluated in accordance with the criteria stated above for scientific/technical merit by an appropriate peer review group. Applications assigned to the AHCPR and that request total direct costs in excess of \$250,000 will be reviewed extensively by the National Advisory Council for Health Care Policy, Research and Evaluation. Secondary review of applications will be by the appropriate National Advisory Council.

AWARD CRITERIA

Applications will compete for available funds with all other applications. The following will be considered in making funding decisions: Quality of the proposed project as determined by peer review, availability of funds, and program balance among research areas of the announcement.

INQUIRIES

Those considering applying in response to this PA are strongly encouraged to discuss the project with AHCPR program administrators in advance of formal submission. The opportunity to clarify any issues or questions from potential applicants is welcome. Direct inquiries regarding programmatic issues to:

Margaret VanAmringe, Director
Center for Research Dissemination and Liaison
Agency for Health Care Policy and Research
2101 East Jefferson Drive, Suite 501
Rockville, MD 20892
Telephone: (301) 227-8362

Direct inquiries regarding fiscal matters to:

Ralph Sloat
Grants Management Officer
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 601
Rockville, MD 20857
Telephone: (301) 227-8447

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.180 and 93.226. Awards are made under authorization of the Public Health Service Act, Title IX, as amended (Public Law 101-239) and administered under PHS grants policies and Federal Regulations 42 CFR 67, Subpart A and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372.

INTERNATIONAL AIDS EPIDEMIOLOGY RESEARCH

NIH GUIDE, Volume 21, Number 10, March 13, 1992

PA NUMBER: PA-92-52

P.T. 34; K.W. 0715008, 0785055, 0710030

National Institute of Allergy and Infectious Diseases

Application Receipt Dates: January 2, May 1, September 1

PURPOSE

The purpose of this program announcement is to stimulate international collaborative research and research infrastructure development for the investigation of a broad range of studies on the epidemiology of Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS) in foreign countries.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, International AIDS Epidemiology Research, is relevant to the priority area of HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-0325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Research grant applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Both foreign and domestic institutions are eligible to be the grantee institution, although all grant applications must include the participation of both eligible U.S. and foreign institutions. Applications from minority individuals and women are encouraged.

MECHANISMS OF SUPPORT

The mechanism of support will be the individual research project grant (R01). Policies that govern research grant programs of the National Institutes of Health will prevail.

RESEARCH OBJECTIVES

Applications are encouraged in areas relevant to the purpose of this program announcement. Research may include, but is not limited to:

- o study of the natural history of HIV infection;
- o identification of populations at high risk of HIV infection;
- o establishment of seroprevalence and seroincidence rates in selected population groups;
- o identification of behavioral and biological co-factors associated with HIV transmission and/or disease acquisition;
- o study of the clinical evolution of HIV and associated diseases;
- o assessment of immunological parameters of HIV infection acquisition and disease development;
- o correlation of HIV genetic variants with disease presentation and/or progression;
- o evaluation of biological and/or clinical markers of HIV infection and associated disease development;
- o assessment of HIV intervention strategies; and

- o pilot studies of preventive and therapeutic strategies.

Applicants are encouraged to give high priority to research designs that promote technology transfer, development of foreign research infrastructure, and the development of self-direction and self-sufficiency in the foreign country research team.

Applications for small-scale intervention studies (e.g., clinical trials of behavioral interventions or sexually transmitted diseases treatment programs) will fall within the purview of this program announcement if these studies are logically linked to the epidemiology studies, if they can be demonstrated appropriate for the given developing country, and if they are complementary to, and not redundant with, work that is already well supported.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions that disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E. Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applicants are to use the research grant application form PHS 398 (rev. 9/91). For purposes of identification and processing, check "yes" on item 2 of the face page of the application and enter the title: "PA-92-52, International AIDS Epidemiology Research." Applications will be accepted in accordance with the standard submission dates for new investigator-initiated AIDS research grant applications: January 2, May 1, and September 1.

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, MD 20892, telephone (301) 496-7441.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for scientific and technical merit by study sections (specifically assigned to review AIDS applications) of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by an appropriate national advisory council or board.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions: quality of the proposed project as determined by peer review; availability of funds; and program balance among research areas of the announcement.

INQUIRIES

Questions regarding programmatic aspects of this program announcement may be directed to:

Robert D. Fischer, M.D., M.P.H.
Deputy Branch Chief for International Health
Epidemiology Branch, CRP, DAIDS
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-6177
FAX: (301) 402-0443

FOR EXPRESS MAIL CORRESPONDENCE WITH DR. FISCHER, USE THE SAME ADDRESS ABOVE WITH THE EXCEPTION OF THE CITY AND ZIP. INSTEAD OF "BETHESDA, MD 20819", USE "ROCKVILLE, MD 20852."

Questions regarding fiscal matters may be directed to:

Ms. Jane Unsworth
Chief, DAIDS Section, Grants Management Branch
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard, Solar Building
Bethesda, MD 20892
Telephone: (301) 496-6177
Fax: (301) 402-1506

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.856 Microbiology and Infectious Diseases Research, and No. 93.855 Allergy, Immunology, and Transplantation Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Authority for the international aspects of this program are provided by Public Law 86-610, the "International Health Act of 1960" and Public Law 100-607, the "Health Omnibus Program Extension Act of 1988."

**THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:

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National Institutes of Health

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21, No. 11
March 20, 1992

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NOTICESAVAILABILITY OF SHORT-TERM RESEARCH TRAINING POSITIONS ON INSTITUTIONAL NATIONAL RESEARCH SERVICE AWARDS FOR STUDENTS IN HEALTH-PROFESSIONAL DEGREE PROGRAMS

NIH GUIDE, Volume 21, Number 11, March 20, 1992

P.T. 44; K.W. 0720005, 0502000

National Institutes of Health

The NIH hereby announces the availability of short-term training positions for health-professional students on National Research Service Award (NRSA) predoctoral or postdoctoral institutional research training grants (T32). These short-term training positions are part of a continuing effort to increase the involvement of physicians and other clinically trained individuals in biomedical and behavioral research and particularly clinical research.

Short-term research training positions are available to students in schools that grant degrees in medicine, osteopathy, optometry, pharmacy, dentistry, and chiropractic and veterinary medicine. These schools, for the purpose of this announcement, are termed health-professional schools. Short-term research training positions are intended to provide health-professional students with an opportunity for a time-limited exposure to research during "off-quarters" and summer periods and an opportunity to consider a career in research. Students selected for this program are encouraged to engage in at least two but no more than four short-term training appointments during the period of their professional predoctoral training. The NIH may not obligate more than 4 percent of the total NRSA budget on short-term research training, consistent with P.L. 99-158.

Institutions may incorporate a request for short-term research training positions into new or competing continuation institutional research training grant applications beginning with the May 10, 1992 receipt date. Existing training grants with three or more years remaining in the award period may request short-term training positions as a competitive supplement for the September 10, 1992 and subsequent receipt dates. Prospective applicants are strongly advised to contact the appropriate NIH program administrator for specific information about application procedures and other special requirements.

Specific guidelines for short-term traineeships are as follows:

Eligibility: Eligible trainees are those students who have completed at least one quarter at an accredited health-professional school prior to participating in the program. Trainees need not be enrolled at the applicant institution. National Research Service Awards cannot be used to support training which leads to the M.D., D.O., D.D.S., D.V.M., or any other health professional degree. Individuals holding an M.S. or Ph.D. degree in the health sciences are not eligible for these awards. Additionally, students matriculated in a formal program leading to an M.S., a Ph.D., an M.D./Ph.D. or a similar research degree are not eligible for short-term research training positions. Within schools of pharmacy, only individuals who are candidates for the Pharm.D. degree are eligible.

Citizenship Requirements: Appointees must be citizens or noncitizen nationals of the United States, or must have in their possession an Alien Registration Receipt Card (1-151 or 1-551) at the time of appointment. Individuals on temporary or student visas are not eligible.

Duration: A given short-term appointment usually will not be shorter than two months nor longer than three months. Participating institutions are encouraged to appoint trainees that are interested in reappointments in future years, so that each student receives more than one period of exposure to research training. Future applications for continued short-term training will be judged in part on the success of the institution in achieving multiple quarter-year appointments for the same student. Thus, students in the final year of health-professional training would not usually be eligible for a first appointment to a short-term traineeship; exceptions to this policy may be requested from the NIH awarding component. Appointments longer than three months are permissible, but, if a health-professional student plans to interrupt his or her studies for a year or more of full-time research training, a regular predoctoral position on the training grant should be used.

Effort: Trainees must engage in full-time research training during the period of the appointment.

Reporting Requirements: In the same fashion as other trainees appointed to research training grants, short-term trainees must complete and return to the NIH a Statement of Appointment Form (Form PHS 2271, revision 10/91) and a Payback Agreement Form (Form PHS 6031, revision 10/91). These forms must be completed and returned at the beginning of each appointment or reappointment. At the end of each appointment, a Termination Notice (Form PHS 416-7, revision 10/91) must be completed and returned to the NIH.

NRSA Service Payback Obligation: Since the time spent in short-term research training will usually total less than twelve months, short-term trainees will usually have no service payback obligation. The time spent in NRSA support is, however, accrued along with any future NRSA support in calculating the total service obligation. This obligation requires that any NRSA support in excess of twelve months be repaid by an equal period of health-related research or health-related teaching. Short-term trainees, therefore, must be advised of the service payback requirement before an appointment to the training grant is offered. Specific information about the NRSA service payback requirement is available in the Guidelines for NRSA Individual Awards - Institutional Grants, NIH Guide for Grants and Contracts, Vol. 13, No. 1, January 6, 1984.

Number of Short-Term Training Positions on an Institutional Research Training Grant: The number of positions requested should be coordinated with the NIH awarding component and must not interfere in any way with the regular research training program.

Stipends: Trainees appointed to short-term research training positions will receive a stipend of \$734 per month.

Training Related Expenses: The institution may receive up to \$125 per month to offset the cost of tuition, fees, travel, supplies and other expenses. For these positions, tuition and fees cannot be requested separately.

Indirect Costs: An indirect cost allowance up to 8 percent of the direct cost of the stipends for short-term research trainees will be paid to the institution, consistent with NIH policy on Institutional Research Training Grants.

Application Characteristics: Applicants for research training grants who wish to include a request for a short-term research training program must use the instructions for Institutional Research Training Grants included with Form PHS 398. Information on the short-term research training program must be included in the application for the regular research training program, but should be separated from the description of the regular program within each section of the application. In addition to the information requested in the section called the Program Plan, the applicant should also address the relationship of the proposed short-term program to the regular research training program and provide assurance that the short-term program will not detract from the regular program. Applicants are reminded that the 25 page limit on the narrative section must be observed.

Review Criteria: Review criteria for short-term training include:

- o the quality of the proposed short-term training program including the commitment of the participating faculty, the program design, the availability of research support, and the training environment,
- o access to candidates for short-term training and the ability to recruit high quality short-term trainees from the applicant institution or other health professional schools,
- o the characteristics of the training program that might be expected to persuade short-term trainees to consider academic/research careers, particularly in clinical areas,
- o the success in attracting students back for multiple short-term appointments,
- o the effects of the short-term training program on the quality of the regular research training program including the appropriateness of the number of short-term positions, and the plan to integrate the short-term training program into the regular research training program,
- o the plan to follow former trainees and assess the effect of such training on their careers.

NIH GUIDE, Volume 21, Number 11, March 20, 1992

P.T. 44; K.W. 0720005, 1014006

National Institutes of Health

In October, 1989, the NIH issued a report titled the Review of the NIH Biomedical Research Training Programs, hereafter called the Review, which summarized the recommendations of three NIH Task Forces on Research Training established by then NIH Director, Dr. James Wyngaarden. These Task Forces recognized the important role of the NIH research training programs in the development of productive researchers and the advancement of biomedical sciences. They also reiterated the NIH commitment to ensuring the training of an adequate number of individuals with appropriate skills to meet future personnel needs in biomedical research. After a careful analysis of existing programs, the Task Forces developed a series of recommendations designed to enhance those aspects of institutional training programs known to be correlated with the production of successful researchers. Many of these recommendations will be implemented by the modification of the review criteria to emphasize the record of successfully placing former trainees into research intensive positions. The changes outlined in this notice are designed to improve the efficiency of the NIH funded research training programs.

The four policy changes listed here will be administered through the initial review process. Revised review criteria for all T32 institutional research training grants will be presented near the end of this notice. These criteria will be in place beginning with applications received for the May 10, 1992 receipt date. In some cases, compliance with the revised policy will be phased in and reviewers will be instructed to take the date of implementation into account. In other cases, the proposed modifications will not represent a significant departure from existing policy. Applicants are advised to consult with the appropriate NIH program administrator to determine the best way to emphasize information in their applications related to these policy directives. A clear presentation of related information will facilitate the peer review process.

1. Emphasize Past Performance of the Training Program at Review.

Background: Based on information discussed in the Review, the single best predictor of future success for a research training program is the record of past performance in terms of producing trainees who remain engaged in research careers.

Policy Implementation: Program directors on all competing and non-competing research training grants are expected to select postdoctoral trainees who are genuinely interested in a career in research. Additionally, postdoctoral trainees already appointed to research training grants are expected to enter research careers after termination. Competing renewal applications submitted for the May 10, 1992 and subsequent receipt dates are to include detailed information related to the activities of all trainees supported by the training grant who have terminated during the last ten years as specified in the instructions to Form PHS 398 (rev. 9/91). In addition, non-competing renewal applications are to contain information on research involvement for all trainees who terminated during the previous budget period. Evidence of research involvement should include information on employment, publications, grants, and any other relevant information.

Review: Beginning with competing renewal applications received for the May 10, 1992 receipt date, reviewers will focus on the research involvement of former NRSA trainees taking into consideration the date of implementation of this policy. Certainly, trainees appointed after July 1, 1992 should have been informed about the purpose of NRSA support and the expectation that a career in research is the anticipated outcome. Training programs in which there has been a consistent pattern of transition to an active research career after termination will be considered favorably at review. On the other hand, training programs in which few former trainees are participating in research activities will be considered less meritorious.

2. Minimum Two Year Training Periods for Health-Professional Postdoctoral Trainees.

Background: Data presented in the Review showed very clearly that postdoctoral trainees with longer periods of appointment to an institutional research training grant were more likely to apply for and receive PHS research grant support. This trend was especially pronounced for postdoctoral trainees with the M.D. degree. The NIH is, therefore, emphasizing a policy that encourages all health-professional postdoctoral trainees appointed to a research training grant to commit at least two years to research or research training. For the purpose of this policy, individuals who have the M.D., D.O., D.D.S., D.V.M., or similar clinically related doctoral degrees are considered to be health-professionals.

The Review also recognized that it would be inappropriate to limit all trainees to appointments on research training grants that last two or more years because there may be other more appropriate training and research opportunities available. In some cases, for example, it may be appropriate for a postdoctoral trainee to obtain a second year of support from an individual fellowship, from a career award, or from a research grant¹. The important concept, however, is that more than one year of postdoctoral research experience is necessary to develop an independent research career.

Policy Implementation: Beginning with competing and non-competing training grants made from fiscal year 1992 funds, training program directors will be expected to be more selective in appointments to research training grants so that appointments to be filled by health-professional postdoctoral trainees are preferentially given to individuals who are willing to engage in a research career and are willing to devote at least two years to research training or some other research related activity. Additionally, health-professional postdoctoral trainees who are currently appointed to positions on training grants are to be strongly encouraged to remain

¹The National Eye Institute encourages postdoctoral trainees to obtain other support for the second and subsequent years of postdoctoral research experience.

in research or research training for at least two years.

Applications for competing renewal research training grants beginning with the May 10, 1992 deadline are to include information on the duration of appointment for all trainees who have terminated during the previous 10 years. For each trainee who terminated before receiving at least two years of research training, the application must also contain an explanation for the short appointment and whether the former trainee's activities subsequent to termination involved research or additional research training.

Non-competing T32 applications submitted on or after September 10, 1991 must also contain information on the duration of support for all NRSA trainees that terminated during the previous budget period. Support periods of less than two years must be followed by an explanation of post-termination activities in the narrative section.

Review: Beginning with competing renewal applications received for the May 10, 1992 receipt date, reviewers will consider the duration of research training and other research activities in the determination of quality. If there is a consistent pattern of appointment of health-professional postdoctoral trainees for periods less than two years with no indication of subsequent research involvement, it will detract from the assessed merit of the grant application. Of course, the Initial Review Group will take into consideration the date this policy was implemented. For example, all appointments made after July 1, 1992 should reflect compliance with this policy. The duration of the research or research training experience for health professional trainees will also be considered in non-competing research training grants received after May 10, 1992.

3. Encourage Postdoctoral Trainees to Apply for Independent Training or Career Development Support After Training on an Institutional Research Training Grant.

Background: Several studies on career patterns of former NRSA recipients have shown that individuals who compete for and receive individual postdoctoral fellowship support are more likely to apply for and receive PHS research grant support than individuals supported solely on research training grants. It is, therefore, in the best interest of postdoctoral trainees to move from a training grant experience to an individual support mechanism such as an individual postdoctoral fellowship, a clinical investigator award, a FIRST award, or a physician/dental scientist award at an appropriate time. It is felt that in many cases postdoctoral trainees will be ready for this transition after completion of one or two years of research training on a research training grant. At that point, most postdoctoral trainees are still in need of further supervised research experience but they should have gained the ability to contribute substantially to the development of a competitive application for individual support. Obviously, health-professional postdoctoral trainees engaged in training leading to a graduate degree might require longer periods of support from a research training grant.

Policy Implementation: By one year from implementation of this policy (May 1993), program directors of research training grants should have established a record of encouraging postdoctoral trainees, who have had one or more years of support from the research training grant, to apply for individual support for further research training or career development. Applicants for competing renewal research training grants are advised to document instances in which trainees have converted to individual support mechanisms such as fellowships, research grants, and career awards. Applications for non-competing renewals should indicate instances of transfer to individual funding for all trainees who terminated during the previous budget period.

Review of Applications: Reviewers will be instructed to examine renewal applications for evidence that postdoctoral trainees have been encouraged to convert to individual support mechanisms. A pattern of application for or receipt of individual fellowships, career awards, or research grants after termination will be considered favorably at review.

4. When Health-Professionals are included in a postdoctoral research training program, the training program will be given special consideration during review if the program incorporates concomitant training of health-professionals with individuals trained in the basic sciences (e.g., individuals with the Ph.D.). **Background:** Data discussed in the Review indicate that M.D. trainees who are supported on training grants that include Ph.D. trainees are more likely to apply for and receive independent NIH research support than M.D. trainees who train only with other M.D. trainees. It was therefore recommended that training programs which in the past have exclusively supported postdoctoral research training for health-professionals should consider shifting the focus of the program to include more fundamental approaches in order to attract Ph.D.s. The overall objective is to enhance the focus on research and research related activities in order to improve the likelihood that the health-professionals who finish the training program will have had sufficient experience to launch an independent research career.

Policy Implementation: Beginning with all institutional research training grants received for the May 10, 1992 receipt date, program directors on training grants that typically train health-professional postdoctoral trainees should consider modifying the training environment in order to make the program more attractive to individuals interested in basic research questions. For example, an integration of training for M.D.s and Ph.D.s could be achieved by developing active linkages with basic science departments through joint appointments for the training faculty or by creating training experiences that involve collaboration between the clinical department and basic science departments. Other modifications of the program to increase the exposure of health-professional trainees to basic research should also be considered. One measure of success would be the appointment of postdoctoral trainee(s) with the Ph.D. or equivalent degrees. It is recognized that such an integration may not be feasible for all training programs.

Review: Initial Review Groups will evaluate the program plan to assess whether or not trainees with health-professional doctorates receive a proper grounding in basic sciences and are provided with exposure to basic biomedical or behavioral research during the training period. Initial Review Groups will also consider the appropriateness of such plans to the overall goals and focus of the training program. When appropriate, the establishment of linkages with basic science departments and the concomitant postdoctoral training of physicians or dentists with individuals with doctorates in the basic sciences (Ph.D.s) will be considered as one indicator of a meritorious research training program.

COMBINED, MODIFIED REVIEW CRITERIA

These four policy modifications will result in an increased emphasis on the past success of the training program in producing biomedical or behavioral researchers. Beginning with applications received for the May 10, 1992 receipt date, initial review groups will consider the following criteria when assessing the merit of a research training grant application:

- o Past research training record for both the program and the designated preceptors in terms of the rate at which former trainees establish independent and productive research careers
- o Past research training record in terms of the success of former trainees in obtaining individual awards such as fellowships, career awards, and research grants for further development
- o Objectives, design, and direction of the research training program
- o Caliber of preceptors as researchers including successful competition for research support
- o Training environment including the institutional commitment, the quality of the facilities, and the availability of research support
- o Recruitment and selection plans for appointees and the availability of high quality candidates
- o The record of the research training program in retaining health-professional postdoctoral trainees for at least two years in research training or other research activities
- o When appropriate, the concomitant training of health-professional postdoctorates (e.g., individuals with the M.D., D.O., D.D.S.) with basic science postdoctorates (e.g., individuals with a Ph.D., Sci.D.) will receive special consideration

NOTICES OF AVAILABILITY (RFPs AND RFAs)

CLINICAL CORRELATIVE STUDIES IN SOLID TUMORS

NIH GUIDE, Volume 21, Number 11, March 20, 1992

RFA AVAILABLE: CA-92-12

P.T. 34; K.W. 0715035, 0745005, 0795005, 0745020

National Cancer Institute

Letter of Intent Receipt Date: May 29, 1992

Application Receipt Date: July 10, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The Cancer Therapy Evaluation Program (CTEP) of the Division of Cancer Treatment (DCT) and the Cancer Diagnosis Branch (CDB) of the Division of Cancer Biology, Diagnosis and Centers (DCBDC) at the National Cancer Institute (NCI) invite applications for cooperative agreements from institutions or consortia, such as DCT Clinical Trials Cooperative Groups, capable of and interested in performing clinical correlative studies with new prognostic factors ready for large scale evaluation. These factors must be relevant to the cancer treatment or clinical outcome of patients with solid tumors. It is essential for institutions to have access to sufficient numbers of patients on phase III clinical protocols to be able to test correlative hypotheses.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Clinical Correlative Studies in Solid Tumors, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic non-profit and for-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications may be submitted from one institution or may include arrangements with one or more additional institutions, if appropriate. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Support of this program will be through the cooperative agreement (U01), an assistance mechanism in which substantial NCI programmatic involvement with the recipient during performance of the planned activity is anticipated. Applicants will be responsible for the planning, direction, and execution of the proposed project. Except as otherwise stated in the RFA, awards will be administered under PHS grants policy as stated in the

This RFA is a one-time solicitation. However, should it be determined that there is a sufficient continuing program need, the NCI will invite recipients of awards under this RFA to submit competitive continuation cooperative agreement applications for review.

FUNDS AVAILABLE

Approximately \$2,000,000 in total costs per year for four years will be committed to fund applications submitted in response to this RFA. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. It is anticipated that ten to twelve awards will be made. The total project period for applications submitted in response to the present RFA may not exceed four years. The earliest feasible start date for the initial awards will be April 1993. Although this program is provided for in the financial plans of the NCI, the award of cooperative agreements pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The objectives of this RFA are to foster collaborations and interactions between basic researchers and clinical investigators in the advancement of therapeutic clinical research and to conduct correlative studies in solid tumors on new prognostic factors that are ready for large-scale evaluation. The CTEP and the CDB invite cooperative agreement applications from institutions or consortia, such as the DCT Clinical Trials Cooperative Groups and the NCI Cancer Centers, capable of and interested in performing clinical correlative studies relevant to cancer treatment or clinical outcome in patients with solid tumors.

Solid tumors, e.g., breast, prostate, lung, colorectal, upper aerodigestive, ovary, bladder, pancreas, melanoma, stomach, kidney, and rarer tumors such as pediatric and adult brain and sarcoma, which are relevant to this RFA, account for significant cancer incidence, morbidity and mortality. Special consideration will be given to studies with colorectal, breast, ovarian, lung, and prostate tumors. Institution-applications are expected to be focused on a specific solid tumor. Applicants may propose to undertake several correlative studies relevant to the specific solid tumor during the grant funding period (up to four years). An individual scientist or a consortia of institutions may be included on more than one application.

The correlative studies should be based on strong and testable hypotheses. A clear rationale must be given for the experimental design and technical methodologies selected. The hypotheses tested must relate to potential clinical applications such as development of new treatment strategies or identification of patient subsets for specific treatment approaches. Preliminary data from appropriate tumor models or analysis of patient specimens must be provided to support the feasibility of each study. Assays must have already been demonstrated to be applicable to tissue samples and/or body fluids. The laboratory assays must utilize tumor specimens from patients receiving defined treatments in large clinical trials such as phase III clinical protocols. Applications will be considered responsive only if investigators have access to sufficient numbers of patient specimens. All investigators are encouraged to work with multi-center organizations or form a consortium of institutions in order to access sufficient numbers of patients and clinical information to test the proposed hypotheses. To coordinate the above activities, each institution must have access to a Central Operations Office and Statistical Center as defined in the RFA.

The cooperative approach outlined in this RFA allows for interactions among successful applicants and is designed to optimize use of patient resources, tissues, reagents, and methods.

SPECIAL REQUIREMENTS

The RFA describes the complete terms for this cooperative agreement including terms of cooperation, nature of participation by NCI staff, responsibilities of the awardees, and the arbitration process to resolve disputes. Special instructions for preparation of cooperative agreement applications are also included.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 29, 1992, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which the application is being submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is requested in order to provide an indication of the number and scope of applications to be reviewed.

The letter of intent is to be sent to:

Ms. Diane Bronzert
Program Director, Cancer Therapy Evaluation Program
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

APPLICATION PROCEDURES

Applications must be received by July 10, 1992. The research grant application form PHS 398 (rev. 9/91) is to be used in applying for cooperative agreements. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892, telephone (301) 496-7441; and from the NCI Program Director named below.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the Division of Research Grants for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to the program requirements and criteria stated in the RFA is an NCI program staff function. Applications that are judged non-responsive will be returned to the applicant. Questions concerning the responsiveness of proposed research to the RFA are to be directed to program staff (see INQUIRIES). Applications may be triaged by an NCI peer review group on the basis of relative competitiveness. The NCI will withdraw from further competition those applications judged to be noncompetitive for award and notify the applicant and institutional business official. Those applications judged to be both competitive and responsive will be further evaluated for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NCI. The second level of review will be provided by the National Cancer Advisory Board.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Ms. Diane Bronzert
Program Director, Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

or

Dr. Sheila E. Taube
Chief, Cancer Diagnosis Branch
Division of Cancer Biology, Diagnosis and Centers
National Cancer Institute
Executive Plaza South, Room 638
Bethesda, MD 20892
Telephone: (301) 496-1591
FAX: (301) 402-1037

Direct inquiries regarding fiscal matters to:

Ms. Mable Lam
Grants Management Specialist
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 242
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 48
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No 93.395, Cancer Treatment Research. Awards are made under authorization of the Public Health Service Act, Title IV Sections 301, 410, and 411, Part A (Public Law 78-410, 42 USC 241 as amended, Public Law 99-158, 42 USC 285a) and administered under PHS grants policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

BI-COMPARTMENT TRANSDERMAL CONTRACEPTIVE DELIVERY SYSTEM

NIH GUIDE, Volume 21, Number 11, March 20, 1992

RFP AVAILABLE: NICHD-CD-92-11

P.T. 34; K.W. 0750020, 0740021, 0760025

National Institute of Child Health and Human Development

The Contraceptive Development Branch, Center for Population Research, National Institute of Child Health and Human Development, has a requirement for the development of a bi-compartment transdermal contraceptive system capable of delivering a progestin from one compartment and an estrogen from the other compartment in such a way

that the delivery of progestin(s) will be independent of the delivery of the estrogen and vice versa. The overall size of the bi-compartment transdermal contraceptive system should be about 10cm².

The objective of the project is to design and develop a transdermal contraceptive system that will have the potential of (1) using one of the several progestins currently used in various oral contraceptive formulations and estradiol-17beta as the estrogen, (2) delivering the progestin or the estrogen alone, and (3) changing the delivery of the progestin(s) and/or the estrogen without affecting the delivery of the other drug. The blood concentration of the contraceptive drug(s) must be comparable to that achieved through oral contraceptive regimen(s) containing that progestin.

Organizations (and their collaborators, if any) must have adequate facilities to perform all necessary in vitro and in vivo animal studies preliminary to filing an Investigational New Drug (IND) application with the Food and Drug Administration, conduct Phase I Clinical Studies, and supply a sufficient number of the bi-compartment transdermal delivery systems for Phase II studies. The Phase II studies will not be a part of this project.

This announcement is not a Request for Proposals (RFP). The RFP will be issued on or about March 20, 1992. Proposals will be due approximately 60 days thereafter. NICHD expects to fund two contracts from this solicitation. Copies of RFP may be obtained by sending written requests to:

Paul J. Duska, Contracting Officer
Contracts Management Branch, OGC
National Institute of Child Health and Human Development
Executive Plaza North, Room 610
9000 Rockville Pike
Bethesda, MD 20892-9903
FAX: (301) 402-0915

ONGOING PROGRAM ANNOUNCEMENTS

CYTOKINES IN AUTOIMMUNITY

NIH GUIDE, Volume 21, Number 11, March 20, 1992

PA NUMBER: PA-92-54

P.T. 34; K.W. 0715015, 0740023, 0760020, 0765033

National Institute of Allergy and Infectious Diseases

PURPOSE

The Division of Allergy, Immunology and Transplantation (DAIT) of the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), invites research project grant applications (R01 and R29) for support of basic studies on the involvement of cytokines in the immunopathogenesis of autoimmune diseases and on their use as modulators of disease initiation and activity.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Cytokines in Autoimmunity, is related to the priority area of diabetes and chronic disabling diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-0325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Research grant applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged. Foreign institutions are not eligible to apply for the First Investigator Research Support Transition (FIRST) Award (R29).

MECHANISMS OF SUPPORT

The mechanisms of support will be the individual research project grant (R01) and the First Investigator Research Support Transition (FIRST) Award (R29). Policies that govern research grant programs of the National Institutes of Health will prevail.

RESEARCH OBJECTIVES

During the last ten years, there have been great advances in the understanding of the biology and biochemistry of cytokines and of the mechanisms leading to autoimmune diseases. However, the precise role that cytokines have in susceptibility to, and promotion, initiation, and perpetuation of, autoimmune responses and induction of tissue injury remain largely unknown. One of the goals of the NIAID in this area is to promote research to achieve a better understanding of the pathogenic role of cytokines in self reactivity and autoimmune diseases. This knowledge will make a critical contribution to advance the opportunities for the development of new, specific and effective therapies for autoimmune diseases.

Areas of interest include:

- o Identification and characterization of known and newly discovered cytokines involved in proliferation and function of autoreactive B cells
- o Analysis of cytokine involvement in the regulation of MHC molecule-self peptide expression in lymphoid cells and target tissues
- o Regulation of autoreactive T-cell functions by cytokines
- o Studies of cytokine effects on the generation and function of CD5+ B cells
- o Characterization of cytokine production and cytokine responses in monocytes and macrophages from autoimmune individuals
- o Research on cytokine signal transduction pathways in autoreactive cells
- o Studies on the role of cytokines in the induction or acceleration of disease in the autoimmune prone host
- o Studies on cytokine receptor modulation as a means of affecting disease development
- o Identification of the cytokine cascades leading to focal inflammation
- o Effects of cytokines and cytokine antagonists in tissue injury and repair during autoimmune diseases

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions that disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Section 2, 1-4 of the Research Plan AND summarized in Section 2, E. Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applicants are to use the standard research grant application form PHS 398 (rev. 9/91). For purposes of identification and processing, check yes on item 2 of the face page and enter the title: "PA-92-54: Cytokines in Autoimmunity". Applications will be accepted in accordance with the standard submission dates for new applications: February 1, June 1, and October 1.

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, MD 20892, telephone (301) 496-7441.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by an appropriate national advisory council or board.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions: quality of the proposed project as determined by peer review, availability of funds, and program balance among research areas of the announcement.

INQUIRIES

Requests for additional information or questions regarding the programmatic aspects of this PA may be directed to:

Dr. S. Serrate-Sztein
Division of Allergy, Immunology and Transplantation
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4A20
Bethesda, MD 20892 (20852 if using overnight delivery services)
Telephone: (301) 496-7985
or

Dr. M. Michele Hogan
Division of Allergy, Immunology and Transplantation
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4A20
Bethesda, MD 20892 (20852 if using overnight delivery services)
Telephone: (301) 496-7551
FAX: (301) 402-0175

Direct inquiries regarding fiscal matters to:

Mr. Jeffrey Carow
Chief, Immunology Grants Management Section, GMB, DEA
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B29
Bethesda, MD 20892
Telephone: (301) 496-7075

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.855 - Immunology, Allergic and Immunologic Diseases Research. Grants are awarded under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grants policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

EXERCISE-INDUCED FATIGUE IN CHRONIC FATIGUE SYNDROME

NIH GUIDE, Volume 21, Number 11, March 20, 1992

PA NUMBER: PA-92-55

P.T. 34; K.W. 0715043, 0745030, 0765033, 0745020

National Institute of Allergy and Infectious Diseases

PURPOSE

The National Institute of Allergy and Infectious Diseases invites investigator-initiated research grant applications to explore biologically rational hypotheses concerning exercise-induced fatigue and/or pathogenesis in chronic fatigue syndrome (CFS) patients. The purpose is to gain an understanding of the biologic basis of CFS in humans. Such an understanding could lead to the development of diagnostic markers and therapeutic interventions.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Exercise-Induced Fatigue in Chronic Fatigue Syndrome, is related to the priority area of immunization and infectious diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-0325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Research grant applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) award (R29).

MECHANISMS OF SUPPORT

Applications considered appropriate responses to this announcement are the traditional research project grant (R01) and the FIRST Award (R29).

RESEARCH OBJECTIVES

o Background

CFS is a multisystem syndrome suspected to be triggered by viral infection and characterized by months of debilitating fatigue frequently associated with sore throat, low grade fever, myalgia, headache, gastrointestinal symptoms, and tender lymph nodes. Cognitive deficits, symptoms of depression, and sleep disorder have been reported, and abnormal brain images derived by different techniques have been described. CFS patients are reported to have neuroendocrine response patterns that differ from those of controls. CFS is diagnosed more frequently in women than in men. Patients have a high prevalence of allergies and profiles of T-cell subsets indicate a state of immune activation in severely ill patients. There have been numerous reports of specific immune dysfunctions, but no single impairment has been regularly associated with the syndrome. Similarly, viruses from several taxonomic groups have been reported to be involved, but none as yet has been confirmed to be consistently associated with disease onset or progression.

Many clinical investigators consider the profound fatigue induced by exercise to be an essential feature of the illness. Studies that follow-up on this clinical observation have the potential to provide important insights into the underlying pathogenic mechanisms of CFS.

o Research Objectives and Experimental Approaches

Well-controlled studies with adequate sample sizes are sought to uncover the basis for the debilitating fatigue that follows moderate exercise in CFS patients. For example, it has been postulated that exercise triggers an acquired or inherent exaggerated cytokine responsiveness. This hypothesis is amenable to testing in exercise-challenge studies of CFS patients. Studies to develop algorithms for standardized characterization and comparison of cytokine responsiveness are within the scope of this announcement. Animal studies also are sought that attempt to identify factors associated with viral or other infectious diseases, which predispose to the development of exercise intolerance. Development of animal models would provide the opportunity to critically evaluate other hypotheses related to the pathological consequences of an over-reactive cytokine response.

In clinical studies, clearly specified inclusion and exclusion criteria for case definition are essential [Holmes, et. al., Annals of Internal Medicine: 108, 387-389, 1988]. The proportion of women in patient study groups should be at least 50 percent. Attention must be given to control for the variables, including disease activity, that impact on the parameters under study.

Investigators are referred to a supplement to Reviews of Infectious Diseases that is devoted to considerations in the design of studies of CFS and the choice of methodologies [Reviews of Infectious Diseases, Vol. 13, Supplement 1, January 1991].

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator must be included with the application.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions that disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Section 2, 1-4 of the Research Plan AND summarized in Section 2, E. Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the research grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines indicated in the application kit. Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441. On the first (face) page, item 2a, of the application, the word "Yes" must be checked and the title and number of the announcement typed in the space provided: PA-92-55: EXERCISE-INDUCED FATIGUE IN CHRONIC FATIGUE SYNDROME.

The original and five legible copies of the application should be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications submitted in response to this announcement will be assigned on the basis of established Public Health Service Referral Guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, and in accordance with the standard NIH peer review procedures. Following scientific-technical review of the applications a secondary review will be by the appropriate national advisory council or board.

AWARD CRITERIA

Applications will compete for available funds with all other R01 and R29 applications considered to have significant and substantial merit. The following will be considered when making funding decisions: relative scientific merit, program relevance, availability of funds.

INQUIRIES

Direct inquiries regarding programmatic issues to:

Ann Schluederberg, Sc.D.
Chief, Virology Branch
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3A16
Bethesda, MD 20892
Telephone: (301) 496-7453
Fax: (301) 402-0804

Direct inquiries regarding fiscal matters to:

Mr. Todd Ball
Chief, Microbiology and Infectious Diseases GM Section
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B35
Bethesda, MD 20892
Telephone: (301) 496-7075

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.856, Microbiology and Infectious Disease Research. Grants will be awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NATIONAL RESEARCH SERVICE AWARD INSTITUTIONAL RESEARCH TRAINING GRANTS (T32)

NIH GUIDE, Volume 21, Number 11, March 20, 1992

PA NUMBER: PA-92-56

P.T. 44; K.W. 0720005

National Institutes of Health

PURPOSE

The National Institutes of Health (NIH) will award National Research Service Award (NRSA) institutional grants (T32) to eligible institutions to develop or enhance research training opportunities for individuals, selected by the institution, who are training for careers in specified areas of biomedical and behavioral research. The purpose of the NRSA program is to help ensure that highly trained scientists are available in adequate numbers and in the appropriate research areas and fields to carry out the nation's biomedical and behavioral research agenda.

Preapplication consultation with NIH is highly desirable, especially where predoctoral or short-term training is planned. Contacts are listed in the section on Inquiries, below. Brief descriptions of institutional NRSA research training programs at other Public Health Service Agencies are also listed below.

ELIGIBILITY REQUIREMENTS

For Institutions

Domestic non-profit private or public institutions may apply for grants to support research training programs. The applicant institution must have, or be able to develop, the staff and facilities required for the proposed program. The training program director at the institution will be responsible for the selection and appointment of trainees to receive NRSA support and for the overall direction of the program.

For Trainees

The individual to be trained must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence (i.e., in possession of the Alien Registration Receipt Card I-551 or I-151) at the time of appointment. Individuals on temporary or student visas are not eligible.

Predoctoral Trainees

Predoctoral trainees on regular research training appointments must have received a baccalaureate degree as of the beginning date of their NRSA appointment, and must be training at the postbaccalaureate level in a program leading to the award of a doctor of philosophy of science or an equivalent degree. National Research Service Awards cannot be used to support courses which are required for the M.D., D.O., D.D.S., D.V.M., or any other similar health-professional degree. Individuals who wish to interrupt their medical, veterinary, dental, optometry or other professional school studies for a year or more to engage in full-time research training before completing their professional degrees are eligible; however, prior approval by the NIH is required before such individuals may be appointed to the NRSA institutional research training grant.

Postdoctoral Trainees

Postdoctoral individuals must have received, as of the beginning date of the NRSA appointment, a Ph.D., M.D., D.O., D.D.S., D.V.M., O.D., D.P.M., Sc.D., Eng.D., Dr.P.H., D.N.S., or equivalent degree from an accredited domestic or foreign institution. Certification by an authorized official of the degree granting institution that all degree requirements have been met is acceptable.

Individuals with health-professional degrees appointed to postdoctoral positions are expected to engage in at least two years of research or research training beginning at the time of appointment. After one or two years of research training support, most postdoctoral trainees should be encouraged to seek support for further supervised research experience through individual awards. Such individual awards could include, but are not limited to, individual postdoctoral fellowships, Physician Scientist Awards, Dental Scientist Awards, Clinical Investigator Awards, Clinical Investigator Development Awards, or research grants. It is recognized that transfer to an individual award may not be appropriate for some postdoctoral trainees such as those engaged in research training leading to a graduate degree. In any case, the review of competing renewal applications for research training programs will include a rigorous review of the ability of the training program to retain

individual trainees for at least two years of research or research training experience. Additionally, the ability of the training program to direct postdoctoral trainees into individual support mechanisms and eventually into independent research careers will be carefully examined at review.

Short-Term Health Professional Trainees

Students enrolled in a school of medicine, osteopathy, optometry, pharmacy, chiropractic, dentistry, public health, or veterinary medicine who have completed at least one quarter and are willing to engage in full-time research training for up to three months are eligible for appointment to short-term positions on an institutional research training grant. Individuals holding an M.S., a Ph.D., or an M.D./Ph.D. degree or an equivalent graduate level research degree are not eligible for short-term training positions. Similarly, individuals matriculated in a formal program leading to an M.S., a Ph.D., an M.D./Ph.D. or a comparable graduate level research degree are not eligible for short-term training positions. Within schools of pharmacy, only individuals who are candidates for the Pharm.D. degree are eligible.

MECHANISM OF SUPPORT

General Provisions

Levels of Training

Predoctoral and Postdoctoral Research Training: Applications will be accepted for predoctoral or postdoctoral research training. Predoctoral research training must be at the postbaccalaureate level and must lead to the Ph.D. or a comparable doctorate degree. Postdoctoral research training is for individuals who have received an M.D., a Ph.D. or comparable doctoral degrees. Predoctoral research training will emphasize fundamental training in the basic disciplinary areas while training at the postdoctoral level will emphasize specialized training to meet national research priorities. Training grants are a desirable mechanism for the postdoctoral training of physicians and other health-professionals whose doctoral training usually involves only limited research experience. For such individuals, the training may be a part of a research degree program, but in all cases, health-professional postdoctoral trainees should agree to engage in at least two years of research, research training, or comparable experiences beginning at the time of appointment.

Short-Term Research Training Positions for Health-Professional Students

Beginning with the May 10, 1992 receipt date, applications for NRSA institutional research training grants which request support for regular predoctoral and/or postdoctoral research training may also request short-term positions reserved specifically to train medical or other health-professional students on a full-time basis during the summer or other "off quarter" periods. Short-term appointments are intended to provide health-professional students with opportunities to participate in biomedical and/or behavioral research in an effort to attract these individuals into research careers.

To be eligible for short-term research training positions, health-professional students must have completed at least one quarter in a program leading to a doctorate at an accredited school of medicine, osteopathy, optometry, pharmacy, chiropractic, dentistry, or veterinary medicine prior to participating in the program. Short-term positions should last at least two months but may not last longer than three months. However, back-to-back short-term appointments may be permitted. Students selected for short-term appointments are encouraged to obtain two or more periods of short-term training during the period of studies leading to their health-professional degree.

Types of Training Permitted

NRSA research training grants may not be used to support studies leading to the M.D., D.O., D.D.S., D.V.M. or other similar health-professional degrees. However, students enrolled in health-professional doctoral degree programs may receive support for short-term research training for one or more periods lasting up to three months each. Also, students enrolled in health-professional doctoral degree programs may interrupt their health-professional studies for a year or more to engage in full-time research training before completing their professional degree.

NRSA research training grants may not be used to support residency training, which means postgraduate training for doctors of medicine, osteopathy, dentistry, optometry, podiatry, and nursing or the training of any other individual who is providing health care directly to patients where the majority of the time is spent in non-research clinical training. However, if a specified period of full-time research training is creditable toward specialty board certification, NRSA may support such postdoctoral research training provided the trainee is interested in establishing a research career. Physicians and other health-professionals accepted for a postdoctoral NRSA appointment are expected to engage in at least two years of research or research training starting at the beginning of the appointment.

Trainees are required to pursue their research training on a full-time basis, devoting at least 40 hours per week, as specified by the sponsoring institution, in accordance with its own policies. Research trainees in clinical areas are expected to devote their time to the proposed research training and to confine clinical duties to those which are a part of the research training experience.

Trainees appointed to the training program must have the opportunity to carry out supervised biomedical or behavioral research with the primary objective of extending their research skills and knowledge in preparation for a career in research.

Duration of Support

Institutional NRSA grants may be made for competitive segments of up to five years and are renewable. Awards within an approved competitive segment are normally made in 12 month increments with support for additional

Trainees are customarily appointed for full-time 12 month periods. No trainee may be appointed for less than nine months except with the prior approval of the awarding unit or when health-professional students are appointed to approved short-term research training positions. No individual trainee may receive more than 5 years of aggregate NRSA support at the predoctoral level and 3 years of aggregate NRSA support at the postdoctoral level, including any combination of support from institutional training grants and individual fellowship awards. Any exception to the total duration of trainee support at either the predoctoral or postdoctoral level requires a waiver from the director of the awarding component at the NIH. The grounds for approving extensions of support can be found in the document titled National Research Service Awards - Guidelines for Individual Awards - Institutional Grants, NIH Guide for Grants and Contracts, Vol. 13, No. 1, January 6, 1984.

Recruitment and Appointment of Trainees

The primary objective of the NRSA program is the preparation of qualified individuals for careers in biomedical and behavioral research. Within the framework of the program's longstanding commitment to excellence and projected needs for investigators in particular areas of research, it is important that attention also be given to recruiting individuals from minority groups that are underrepresented nationally in the biomedical and behavioral sciences. Application information on plans for the recruitment of trainees should include a description of steps to be taken for the recruitment of individuals from underrepresented minority groups. Also, competing continuation applications should include cumulative information on the recruitment of minority trainees during the previous award period and the subsequent career development of all trainees, including information about their minority status. Failure to include an adequate plan for recruitment or a report on minority recruitment from the previous award period may result in a delay of funding until that information is provided. Also program directors should be aware of a recruitment pool in the nurse community which may have been overlooked. NRSA program directors should make information about their programs available to the nursing profession.

Consistent with the objectives of the NRSA programs and the focus on the placement of former research trainees into research careers, it has been shown that trainees who leave programs which exclusively train health-professional postdoctorates are less likely to apply for and receive research grant support than health-professionals who train in an environment which also trains postdoctorates with the Ph.D. degree. As a consequence, for training programs which focus, for example, on research training for individuals with the M.D., consideration should be given to the development of linkages with basic science departments or the modification of program focus to attract individuals with the Ph.D., when such changes are consistent with the goals of the program. Applications which indicate that linkages with basic science departments have been established and/or propose the concomitant postdoctoral training of physicians or dentists with individuals who have doctorates in the basic sciences (e.g., individuals with the Ph.D.) will be given special consideration at review.

Payback Provisions

Before trainees can be appointed to a training grant, they must sign an agreement to fulfill the NRSA payback requirements. Recipients agree to engage in health related research and/or health related teaching for a period equal to the period of NRSA support in excess of 12 months. Once an individual has had 12 months of postbaccalaureate NRSA support, all subsequent NRSA support is subject to payback. The period of appointment to a short-term research training positions will be accumulated along with any future NRSA support to calculate the total NRSA service obligation.

Recipients must begin to undertake the obligated service on a continuous basis within 2 years after termination of NRSA support. The period for undertaking payback service may be delayed for additional research training, for temporary disability, for a temporary hardship, for completion of residency requirements, or for completion of the requirements for a graduate degree. Requests for an extension must be made in writing to the awarding unit specifying the need for additional time and the length of the required extension. Recipients of NRSA support are responsible for informing the awarding unit of changes in status or address.

For individuals who fail to fulfill their obligation through service, the United States is entitled to recover the total amount of NRSA funds paid to the individual for the obligated period plus interest at a rate determined by the Secretary of the Treasury. Financial payback must be completed within three years beginning on the date the United States becomes entitled to recover such amount. Under certain conditions, the Secretary of Health and Human Services may extend the period for starting service or for repayment, permit breaks in service, or otherwise waive or suspend the payback obligation of an individual.

Applicant organizational officials responsible for recruitment of trainees should familiarize themselves with the terms of the service payback requirements and explain them to prospective training candidates before an appointment to the training grant is offered.

Stipends and Other Training Costs

The current stipend levels are as follows: Predoctoral trainees at all levels of experience receive \$8,800 per annum. Health professional students appointed to short-term training positions will receive \$734 per month.

For postdoctoral trainees, the stipend for the first year of support is determined by the number of years of relevant postdoctoral experience at the time of appointment. Relevant experience may include research experience (including industrial), teaching, internship, residency, or other time spent in full-time studies in a health-related field following the qualifying doctoral degree. The stipend for each additional year of NRSA support is the next level on the stipend scale. Current postdoctoral stipends are as follows:

Years of Relevant Experience

Years of Relevant Experience	Stipend
0	\$18,600
1	19,700
2	25,600
3	26,900
4	28,200
5	29,500
6	30,800
7 or more	32,300

Trainees with health-professional doctoral degrees who are enrolled in a graduate degree program are considered to be in postdoctoral training and will receive the appropriate stipend listed above.

NRSA stipends may be supplemented by an institution from non-Federal funds. No Federal funds may be used for stipend supplementation unless specifically authorized under the terms of the program from which the supplemental funds are derived. An individual may make use of Federal educational loan funds or V.A. benefits when permitted by those programs. Under no circumstances may the conditions of stipend supplementation detract from or prolong the training.

Trainees may be permitted to receive compensation for services as a research assistant or in some other position on a Federal research grant, provided the services are not related to the trainee's dissertation area or program of training and the services do not interfere with or prolong the research training experience. It is expected that compensation from research grants will occur on a limited part-time basis apart from the normal training activities which require a minimum of 40 hours per week. Such compensation for services related to a research grant is not considered stipend supplementation. More specific information on compensation as a research assistant is available in the Guidelines for NRSA Individual Awards - Institutional Grants, NIH Guide for Grants and Contracts, Vol. 13, No. 1, January 6, 1984.

The Tax Reform Act of 1986, Public Law 99-514, impacts on the tax liability of all individuals supported under the NRSA program. Degree candidates who, prior to the enactment of Public Law 99-514, were able to exclude all monies received under an NRSA award from their reported income may now exclude only course tuition, fees, books, supplies and equipment required for attendance. Non-degree candidates, who formerly were able to exclude from stipends \$300 a month for a period not to exceed 3 years are now required to report all stipends and any monies paid on their behalf for course tuition and fees required for attendance. These new statutory requirements are in force as of January 1, 1987.

NIH is not in a position to advise students or institutions about tax liability. In any event, changes in the taxability of stipends in no way alters the relationship between NRSA fellows, trainees and institutions. NRSA stipends are not now, and never have been, salaries. Trainees supported under the NRSA are not in an employee-employer relationship with NIH or the institution in which they are pursuing research training.

Tuition and fees, including medical insurance for the individual in training, are allowable trainee costs if such charges are required of all persons in a similar training status at the institution, without regard to their source of support. Family medical insurance coverage, however, is not an appropriate charge to the NRSA research training grant. Tuition at the postdoctoral level, if justifiable, is limited to that required for specific courses in support of the approved training program.

Trainee travel, including attendance at scientific meetings, which the institution determines to be necessary to the individual's training, is an allowable trainee expense. In addition to travel to scientific meetings, support for travel to a research training experience away from the grantee institution for periods up to one year may be permitted. Research training experiences away from the parent institution must be carefully justified considering the type of opportunities for training available, how they differ from opportunities offered at the parent institution, and the relationship of the proposed experience to the trainee's career stage and career goals. Requests for training away from the parent institution require prior approval from the NIH. Letters requesting training away from the parent institution may be submitted to the NIH awarding component at any time during the award period.

Institutional costs of up to \$1,500 per year per predoctoral trainee and up to \$2,500 per year per postdoctoral trainee may be requested to defray the costs of other training related expenses, such as staff salaries, consultant costs, equipment, research supplies, and staff travel. The institution may receive up to \$125 per month to offset the cost of tuition, fees, travel, supplies, and other expenses for each short-term research training position. Also, an indirect cost allowance based on 8 percent of total allowable direct costs exclusive of tuition, fees, health insurance, and expenditures for equipment, or actual indirect costs, whichever is less, may be requested. Applications from State and local government agencies may request full indirect cost reimbursement.

APPLICATION PROCEDURES

Application is made on Grant Application Form PHS 398 (revision 9/91). This revision contains special instructions for institutional NRSA research training grants. Applicants are reminded that the 25 page limit on the narrative section must be observed.

Applicants for research training grants who wish to include a request for a short-term research training program should also use the instructions for Institutional Research Training Grants included with Form PHS 398. Short-term positions must be identified separately within each category on the budget page, listing as instructed the number of short-term trainees, the total stipend amount, and the total amount of the training related expenses. Under stipends, short-term positions should be listed under the "Other" category. The description of the short-term research training program must be included in the application for the regular research training program, but must be separated from the description of the regular program within each section of the application. In

addition to the information requested in the section called the Program Plan, the applicant must also address the relationship of the proposed short-term program to the regular research training program and provide assurance that the short-term program will not detract from the regular program.

The Form PHS 398 is usually available at institutional offices of sponsored research or their equivalent. If not available locally, send a request accompanied by a self-addressed mailing label to:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building, Room 449
Bethesda, MD 20892

REVIEW CONSIDERATIONS

Applications are evaluated for merit by NIH initial review groups based on the following criteria:

- o Past research training record for both the program and the designated preceptors in terms of the rate at which former trainees establish independent and productive research careers
- o Past research training record in terms of the success of former trainees in obtaining individual awards such as fellowships, career awards, and research awards for further development
- o Objectives, design, and direction of the research training program
- o Caliber of preceptors as researchers including successful competition for research support
- o Training environment including the institutional commitment, the quality of the facilities, and the availability of research support
- o Recruitment and selection plans for appointees, and the availability of high quality candidates
- o The record of the research training program in retaining health-professional postdoctoral trainees for at least two years in research training or other research activities
- o When appropriate, the concomitant training of health-professional postdoctorates (e.g., individuals with the M.D., D.O., D.D.S.) with basic science postdoctorates (e.g., individuals with a Ph.D., Sc.D.) will receive special consideration

Short-Term Research Training Positions

In addition to the above criteria, applications that request short-term training positions will also be judged on the following criteria:

- o the quality of the proposed short-term training program including the commitment of the participating faculty, the program design, the availability of research support, and the training environment,
- o access to candidates for short-term training and the ability to recruit high quality short-term trainees from the applicant institution or some other health professional school,
- o the characteristics of the training program which might be expected to persuade short-term trainees to consider academic/research careers, particularly in clinical areas,
- o the success in attracting students back for multiple year appointments,
- o the effects of the short-term training program on the quality of the regular research training program including the appropriateness of the number of short-term positions, and the plan to integrate the short-term training program into the regular research training program,
- o the plan to follow former short-term trainees and assess the effect of such training on their subsequent careers.

Minority Recruitment Plan

All applications must include a plan to recruit individuals from underrepresented minority groups. If an application is received without a plan, review may be deferred until a plan is provided. The plan to recruit minorities will be evaluated by the initial review group after the quality of the training grant application has been assessed and the priority score has been assigned. The comments of the review committee on the plan for attracting minority individuals will be presented in a note in the summary statement. For renewal applications, this commentary will also cover accomplishments in recruiting and retaining individuals from underrepresented minority groups during the previous award period. Funding of an application may be delayed if the plan for recruiting underrepresented minorities is considered inadequate, or, in the case of renewal applications, if the report of efforts to recruit minorities during the previous award period is considered inadequate. The plan to recruit minority individuals into any short-term training positions must also be included.

Training in the Responsible Conduct of Research

Applications must include a description of formal or informal instruction that deals with various aspects of scientific integrity or the responsible conduct of research. Specific elements of the plan might include topics

to be covered, faculty to be involved, format of the instruction, and schedule of instruction, however, the exact content of the plan is left to each research training program. The plan to provide instruction in the responsible conduct of research will not be considered in the determination of merit of the overall research training program, but applications that do not contain such a plan will be considered incomplete and an award will not be made until a plan is provided.

Review Schedule

Application Receipt Date	Initial Review Meeting	Council/Board Meeting	Earliest Start Date
Jan 10	Jun	Sep/Oct	Dec 1
May 10	Oct/Nov	Jan/Feb	Apr 1
Sep 10	Feb/Mar	May/Jun	Jul 1

Most institutional training grants have a start date of July 1, but there are other possible start dates. Several Institutes or Centers make funding decisions once a year in January or February, or earlier, in order to provide program directors with an adequate recruitment period. A few Institutes or Centers restrict receipt dates to once a year. For example, the National Institute on Child Health and Human Development (NICHD) and the National Eye Institute (NEI) receive training grant applications only on January 10. The National Institute on Dental Research (NIDR) receives training grant applications only on September 10. And, the National Library of Medicine (NLM), the National Institute on Environmental Health Sciences (NIEHS), and the National Center for Nursing Research (NCNR) receive training grant applications only on May 10. Applicants are strongly encouraged to contact appropriate Institute staff before submitting an application.

AWARD CRITERIA

Final selection will be made based on the review group recommendation, the need for research personnel in specified program areas, and the availability of funds. The Institute will notify the applicant of the final action shortly after the advisory group meeting.

Following initial review, applications are also reviewed by the Council, Board, or other national advisory group to the NIH Institute or Center whose activities relate to the proposed research training. These advisory groups will include among the information they consider the initial review groups' comments on the recruitment of individuals from underrepresented minority groups into the training program.

Additional Information

For additional information, see the document titled National Research Service Awards - Guidelines for Individual Awards - Institutional Grants, NIH Guide for Grants and Contracts, Vol. 13, No. 1, January 6, 1984, usually available at the institution and/or contact the appropriate individual listed under Inquiries, below.

OTHER NRSA INSTITUTIONAL RESEARCH TRAINING PROGRAMS

NIH SHORT-TERM RESEARCH TRAINING FOR STUDENTS IN HEALTH PROFESSIONAL SCHOOLS (T35)

Certain NIH Institutes offer programs exclusively designed to introduce students in health professional schools to the opportunities inherent in a research career by supporting full-time research training during off quarters or summer sessions. In these programs, all of the positions are short-term research training positions and are separate and apart from the regular research training grants described in this document which may include a few short-term research training positions in addition to the long-term predoctoral and/or postdoctoral research training positions. Prospective applicants are strongly encouraged to contact appropriate Institute staff before submitting an application. Announcements for Short-Term Research Training Grants are available from the Office of Grants Inquiries listed above.

SPECIAL PROGRAMS FOR MINORITY INSTITUTIONS

The Minority Access to Research Careers (MARC) Program awards research training grants and fellowships (see next four items) that help increase the number and capabilities of minority biomedical research scientists and strengthen science curricula and research opportunities at institutions with substantial minority enrollments. These programs are administered by the National Institute of General Medical Sciences.

The MARC Honors Undergraduate Research Training Grant helps minority institutions develop strong undergraduate science curricula, stimulate an interest in biomedical research among undergraduate students, and increase the number of well-prepared minority students who can compete successfully for entry into graduate programs leading to the Ph.D. degree in the biomedical sciences. Under this program, minority institutions receive support to provide honors students with science courses, research training, and summer research experience outside the home institution.

The MARC Predoctoral Fellowship provides a further incentive to graduates of the MARC Honors Undergraduate Program to obtain research training in the nation's very best graduate programs.

The MARC Faculty Fellowship offers an opportunity for advanced biomedical research training to selected full-time faculty members of minority institutions. This training can lead to a Ph.D. degree or can involve postdoctoral research, and can be pursued at any nonprofit public or private institution in the United States with suitable facilities. When the training period is over, fellows are expected to return to their sponsoring schools to teach and conduct research.

The MARC Visiting Scientist Program provides support for periods of 3 to 12 months to outstanding scientist-teachers who serve as visiting scientists at eligible minority institutions.

For additional information, write to:

Minority Access to Research Careers (MARC)
National Institute of General Medical Sciences
NIH, Westwood Building, Room 9A-18
Bethesda, MD 20892

INQUIRIES

Applicants are encouraged to contact the individuals designated below, before preparing an application, for additional information concerning the areas of research, receipt dates and other types of preapplication consultation. Contact in advance of submission is especially important for programs requesting support for predoctoral or short-term research training.

NATIONAL INSTITUTE ON AGING (AG)

Dr. Phyllis Eveleth
Deputy Associate Director and Training Officer
Office of Extramural Affairs
National Institute on Aging
Gateway Building, Suite 2C218
Bethesda, MD 20892
Telephone: (301) 496-9322

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (AI)

Dr. Leslye Johnson
Chief, Enteric Diseases Branch
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Westwood Building, Room 748
Bethesda, MD 20892
Telephone: (301) 496-7051

Dr. Eugene Zimmerman
Special Assistant to the Director
Division of Allergy, Immunology, and Transplantation
National Institute of Allergy and Infectious Diseases
Westwood Building, Room 754
Bethesda, MD 20892
Telephone: (301) 496-8973

Ms. Nancy Brown
Health Specialist
Division of Acquired Immunodeficiency Syndrome
National Institute of Allergy and Infectious Diseases
Control Data Building, Room 243P
Bethesda, MD 20892
Telephone: (301) 496-0638

NATIONAL INSTITUTE OF ARTHRITIS & MUSCULOSKELETAL & SKIN DISEASES (AR)

Dr. Richard W. Lynn
Director, Muscle Biology Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 403
Bethesda, MD 20892
Telephone: (301) 496-7495

NATIONAL CANCER INSTITUTE (CA)

Dr. Vincent Cairoli
Chief, Cancer Training Branch
National Cancer Institute
Executive Plaza North, Room 232
Bethesda, MD 20892
Telephone: (301) 496-8580

NATIONAL INSTITUTE OF DEAFNESS AND OTHER COMMUNICATION DISORDERS(DC)

Dr. Daniel Sklare
Program Administrator and Training Officer
Division of Communication Sciences and Disorders
National Institute of Deafness and Other Communication Disorders
Executive Plaza South, Room 400B
Bethesda, MD 20892
Telephone: (301) 496-5061

NATIONAL INSTITUTE OF DENTAL RESEARCH (DE)

Dr. Thomas M. Valega
Special Assistant for Manpower Development and Training
Office of Extramural Programs
National Institute of Dental Research
Westwood Building, Room 510
Bethesda, MD 20892
Telephone: (301) 496-6324

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (DK)

Dr. Lois Lipsett
Division of Diabetes, Endocrinology and Metabolic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 620
Bethesda, MD 20892
Telephone: (301) 496-7433

Dr. Judith Podskalny
Division of Digestive Diseases and Nutrition
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A15
Bethesda, MD 20892
Telephone: (301) 496-7455

Dr. Charles Rodgers
Division of Kidney, Urologic and Hematologic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 621
Bethesda, MD 20892
Telephone: (301) 496-7573

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (ES)

Dr. Annette Kirshner
Program Administrator, Scientific Programs Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-0488

NATIONAL EYE INSTITUTE (EY)

Dr. Ralph Helmsen
Research Training and Research Resources Officer
National Eye Institute
Building 31, Room 6A49
Bethesda, MD 20892
Telephone: (301) 496-5983

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (GM)

Dr. John Norvell
Assistant Director for Research Training
National Institute of General Medical Sciences
Westwood Building, Room 907
Bethesda, MD 20892
Telephone: (301) 496-7260

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (HD)

Ms. Hildegard Topper
Program Analyst
National Institute of Child Health and Human Development
Building 31, Room 2A04
Bethesda, MD 20892
Telephone: (301) 496-0104

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (HL)

Dr. John Fakunding
Chief, Research Training and Development Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 3C04
Bethesda, MD
Telephone: (301) 496-1724

Ms. Mary Reilly
Prevention, Education, and Research Training Branch
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 640
Bethesda, MD 20892
Telephone: (301) 496-7668

Dr. Fann Harding
Division of Blood Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 5A08
Bethesda, MD 20892
Telephone: (301) 496-1817.

NATIONAL CENTER FOR NURSING RESEARCH (NR)
Dr. Laura James
Nurse Scientist Administrator
Acute and Chronic Illness Branch
National Center for Nursing Research
Westwood Building, Room 752
Bethesda, MD 20892
Telephone: (301) 402-3290

Dr. Sharlene Weiss
Chief, Health Promotions and Prevention Branch
National Center for Nursing Research
Westwood Building, Room 757
Bethesda, MD 20892
Telephone: (301) 402-3296

Dr. Barbara Pillar
Nurse Scientist Administrator
Nursing Systems Branch
National Center for Nursing Research
Westwood Building, Room 757
Bethesda, MD 20892
Telephone: (301) 402-2402

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NS)

Mr. Edward Donohue
Division of Extramural Activities
National Institute of Neurological Disorders and Stroke
Federal Building, Room 1016
Bethesda, MD 20892
Telephone: (301) 496-4188

NATIONAL CENTER FOR RESEARCH RESOURCES (RR)

Dr. Harriet Gordon
Medical Officer
General Clinical Research Centers Program
National Center for Research Resources
Westwood Building, Room 10A-03
Bethesda, MD 20902
Telephone: (301) 496-6595.

NATIONAL CENTER FOR HUMAN GENOME RESEARCH (HG)

Dr. Bettie Graham
Chief, Research Grants Branch
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531

NRSA PROGRAMS AT OTHER AGENCIES WITHIN THE PUBLIC HEALTH SERVICE

Agency for Health Care Policy and Research (AHCPR)
AHCPR (formerly the National Center for Health Services Research and Health Care Technology Assessment) is a separate agency of the Public Health Service. AHCPR supports NRSA institutional training grants that allow predoctoral and postdoctoral trainees to gain experience in applying research methods to the systematic analysis and evaluation of health services. For information and application forms, contact the NRSA Project Officer, AHCPR Center for Research Dissemination and Liaison, 2101 East Jefferson Street, Suite 501, Rockville, MD 20852; telephone (301) 227-8362.

Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) ADAMHA is a separate agency within the Public Health Service. ADAMHA includes the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH). These institutes also

provide support through NRSA institutional grants at both the predoctoral and postdoctoral levels. For information and application forms, contact the following offices at the 5600 Fishers Lane, Rockville, MD 20857.

Grants Management Officer
National Institute on Alcohol Abuse and Alcoholism
Room 16-86
Telephone: (301) 443-4703

Grants Management Officer
National Institute on Drug Abuse
Room 10-25
Telephone: (301) 443-6710

Grants Operation Section, Grants Management Branch
National Institute of Mental Health
Room 7C-05
Telephone: (301) 443-4414

Health Resources and Services Administration (HRSA)
HRSA is a separate agency within the Public Health Service. HRSA offers institutional research training grants for research training in primary medical care. These awards permit trainees to gain experience in applying research methods to the systematic analyses and evaluation of primary medical care. For information and application forms please contact the following offices at 5600 Fishers Lane, Rockville, MD 20857:

Grants Management Branch (T32)
Residency and advanced Grants Section
Bureau of Health Professions, HRSA
Parklawn Building, Room 8C-26
Telephone: (301) 443-6002

Programmatic inquiries should be addressed to:

Division of Medicine, BHP/HRSA
Primary Care Medical Education Branch
Parklawn Building, Room 4C-04
Telephone: (301) 443-6820

AUTHORITY AND REGULATIONS

NRSA Institutional Research Training Grants are made under the authority of Section 487 of the Public Health Service Act as amended (42 USC 288). Title 42 of the Code of Federal Regulations, Part 66, is applicable to this program. This program is also described under the following numbers in the Catalog of Federal Domestic Assistance: 93.121, 93.306, 93.361, 93.398, 93.821, 93.837-93.839, 93.846-93.849, 93.853-93.856, 93.859, 93.862-93.868, 93.871, 93.880, and 93.894.

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NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

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This publication is also available electronically to institutions via BITNET or INTERNET. Alternative access is through the NIH Grant Line using a personal computer. Contact Dr. John James at 301/496-7554 for details, or send an E-mail message to ZNS@NIHCU.

NOTICES

ELECTRONIC ACCESS TO NIH GUIDE FOR GRANTS AND CONTRACTS

NIH GUIDE, Volume 21, Number 12, March 27, 1992

P.T. 16; K.W. 1004017, 1014002

National Institutes of Health

The NIH Guide for Grants and Contracts can be obtained electronically by the extramural community in two ways:

- o Electronic Networks to Institutional Hubs (E-Guide)
- o NIH Grant Line, an Electronic Bulletin Board

The advantage of both of these methods is that announcements are available to the extramural community immediately upon publication, without the delay due to mailing the print version. In addition, the full length version of each Request for Applications (RFA) may be obtained from both of the electronic means of dissemination. Use of these means is encouraged.

INSTITUTIONAL HUBS

Institutional subscriptions to the E-Guide, which includes the NIH Guide, the full text of RFAs, indices, and directories, are available upon request. The subscriber, usually located in the Office of Sponsored Research or equivalent, receives the E-Guide via an electronic network (BITNET or INTERNET) once per week, concomitant with the publication of the print version of the NIH Guide. From the point of receipt, the E-Guide may be forwarded in print or electronically, at the discretion of the recipient, to researchers and administrators at that institution.

To express interest in serving as an Institutional Hub, send an E-mail message that includes the name of the designated person, the E-mail address, title, and location of that person, and the estimated number of individuals to whom the E-Guide will be distributed locally. Send the request to Ms. Rebecca Duvall, Program Analyst for the NIH Guide, at BITNET Q2C@NIHCU or INTERNET Q2C@CU.NIH.GOV.

NIH GRANT LINE

Contents

The purpose of NIH Grant Line (known also as DRGLINE) is to make program and policy information of the Public Health Service (PHS) agencies rapidly available to the biomedical research community. Most of the information

available on this bulletin board is derived from the weekly publication, the NIH Guide for Grants and Contracts, and consists of Notices, Notices of Availability of RFAs and Requests for Proposals, Program Announcements, and statements of PHS policy.

The information to be found on the NIH GRANT LINE is grouped into three main sections: (1) short News Flashes that appear without any prompting shortly after logon, (2) Bulletins that are for reading, and (3) Files that are intended mainly for downloading.

The Files section is grouped into ten Directories as follows:

Name	Entries	Description
GENINFO	2	General NIH info, acronyms, receipt dates
GUIDENDX	10	Various indexes to NIH Guide and RFA schedule
GUIDE90	26	Weekly issues of NIH Guide for 1990
GUIDE91	49	NIH Guide, 1991, New Electronic Format
GUIDE92	7	E-GUIDE, 1992, Weekly Electronic Editions
PROGUIDE	13	NIH program announcements and guidelines
RFAS90	42	Full text of 1990 RFAS available electronically
RFAS91	150	Full Text of 1991 RFAs available electronically
RFAS92	15	Full Text of 1992 RFAs available electronically
TELDIR	2	NIH telephone directory, for extramural use

Directories whose names are of the form GUIDEyy (where yy is the year) contain the weekly issues of the NIH Guide for that year. Directories whose names are of the form RFASyy contain the full text of RFAs distributed during that year. Program announcements and guidelines are found in both GUIDEyy and PROGUIDE, but the ones in PROGUIDE are usually applicable to all of NIH, are often grant mechanism oriented, and will be effective for longer periods of time than those in GUIDEyy. Newly announced programs would first appear in the GUIDEyy directories.

To access the NIH GRANT LINE:

1. Configure the terminal emulator as: 1200 or 2400 baud, even parity, 7 data bits, 1 stop bit, Local Echo on.
2. Using the procedure specified in the communication software, dial 1-301-492-2221. When you get a response indicating that you have been connected, type ",GEN1" (don't type the quotes) and press ENTER; you will be prompted for "INITIALS?". Type BB5 and press ENTER. You will then be prompted for "ACCOUNT?". Type CCS2 and press ENTER.

Messages and a menu will be displayed that will allow you to read Bulletins or download Files. On the NIH GRANT LINE, back issues of the NIH Guide are found in two different directories. GUIDE90 has issues going back to July 6, 1990; GUIDE91 has all of the issues in 1991; and GUIDE92 has all of the issues to date in 1992.

The Q (Quit) command returns the user to the Main menu. From there the F (Files) command is used to enter the file processing facility of the bulletin board. Use the D (Directory) command to see general descriptions of the various Directories. Selection of a given Directory, (GUIDENDX for example), will display the names and descriptions of files.

The T (Transfer) command downloads the selected file. After the file has been named and ENTER pressed, one of the downloading options may be selected. To download the file to a personal computer, Option 1 should be selected to obtain instructions in the preparation for downloading.

Although the access to NIH GRANT LINE is through a modem, users who have a Bitnet or Internet address may use Option 2 to mail a file instead of downloading it through the modem. Mailing files can greatly reduce the length of the online interactive session and long distance telephone charges. When a file to be "downloaded" has been selected, chose option 2 to transmit via a network and then respond with the desired E-mail address.

INQUIRIES

Additional information about subscribing as an Institutional Hub may be obtained from:

Ms. Rebecca Duvall
Institutional Affairs Office
National Institutes of Health
9000 Rockville Pike
Building 31, Room 5B31
Bethesda, MD 20892
Telephone: (301) 496-5366

Additional information about the NIH GRANT LINE may be obtained from:

Dr. John James
Division of Research Grants
National Institutes of Health
Westwood Building, Room 109
Telephone: (301) 496-7554

ONCOGENE ANALYSIS FOR MOLECULAR TOXICOLOGY STUDIES

NIH GUIDE, Volume 21, Number 12, March 27, 1992

RFP AVAILABLE: NIH-ES-92-25

P.T. 34; K.W. 1007009, 1002019, 0785140, 0755045

National Institute of Environmental Health Sciences

The primary purpose of this project will be to provide laboratory support by the application of assays to screen for and verify mutations in oncogenes, such as ras or p53, in samples of frozen or fixed tissues using a variety of molecular techniques. Specific methods to be in place include polymerase chain reaction (PCR) amplification, oligonucleotide hybridization, restriction fragment length polymorphism (RFLP) analysis, direct sequencing of PCR products, and single stranded conformation polymorphism (SSCP). Specific tasks include, but are not limited to, DNA extraction, amplification of regions of p53 or other genes, screening for mutational activities of ras or other genes or mutational deactivation of tumor suppressor genes, and assay for loss of heterozygosity. All responsible sources may submit a proposal that will be considered. The Request for Proposals (RFP) for this estimated five-year competitive procurement will be released on or about March 27, 1992. Proposals will be approximately 40 days thereafter. The institute expects to make one award from this solicitation.

Requests must reference RFP NIH-ES-92-25 and must be forwarded to:

National Institute of Environmental Health Sciences
Contracts and Procurement Management Branch
ATTN: Thomas M. Hardee, Contracting Officer
79 T.W. Alexander Drive, 4401 Building
P. O. Box 12874
Research Triangle Park, NC 27709
Telephone: (919) 541-7893

OPERATION OF AN EXPERIMENTAL VIRUS VACCINE PRODUCTION LABORATORY

NIH GUIDE, Volume 21, Number 12, March 27, 1992

RFP AVAILABLE: NIH-NIAID-DIR-93-03

P.T. 34; K.W. 0740075, 1002045, 0715125

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID), NIH, has a requirement for an Experimental Virus Vaccine Production Laboratory. The Division of Intramural Research, NIAID is soliciting contract proposals from organizations having the capabilities and facilities to prepare experimental virus vaccine suspensions for submission to the Center for Biologic Evaluation Research, Food and Drug Administration, using the Code of Federal Regulations (CFR), Number 21, April 1, 1990, as a guide. The viruses will include, but not be limited to: influenza, paramyxoviruses, hepatitis, rotavirus, and vaccinia viruses. The successful offeror must meet the requirements listed in the CFR for an establishment engaged in the preparation of live virus vaccines licensed for human use. The offeror will also be subject to inspection under the "Good Laboratory Practices Act" and "Good Manufacturing Practices Act." The NIAID-sponsored project will take approximately five years to complete. One contract is anticipated.

This is an announcement for an anticipated Request for Proposal (RFP). RFP NIH-NIAID-DIR-93-03 shall be issued on or about March 31, 1992, with a closing date tentatively set for May 29, 1992. Requests for the RFP shall be directed in writing to:

Sylvia Cunningham, Contracting Officer
Contract Management Branch
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3C07
6003 Executive Boulevard
Bethesda, MD 20892

To receive a copy of the RFP, supply this office with two self-addressed labels. All responsible sources may submit a proposal that will be considered. This advertisement does not commit the Government to award a contract.

THE STUDY OF PATIENT OUTCOMES ASSOCIATED WITH PHARMACEUTICAL THERAPY

NIH GUIDE, Volume 21, Number 12, March 27, 1992

RFA AVAILABLE: HS-92-03

P.T. 34; K.W. 0745005, 0795005

Agency for Health Care Policy and Research

Application Receipt Date: July 15, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACTS NAMED IN INQUIRIES, BELOW.

PURPOSE

The purpose of this announcement is to solicit applications from non-profit organizations to conduct research on the outcomes of pharmaceutical therapy. The Agency for Health Care Policy and Research (AHCPR) is encouraging innovative and timely health services research on the effectiveness of pharmaceutical treatment and care.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, The Study of Patient Outcomes Associated with Pharmaceutical Therapy, is related to the section on "Food and Drug Safety" (Objectives 12.5 and 12.6). Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign non-profit organizations, public and private, including universities, clinics, units of State and local governments, non-profit firms, and non-profit foundations. For-profit institutions are not eligible for AHCPR grants. Applications from minority and women investigators are encouraged.

MECHANISM OF SUPPORT

The RFA will use the research grant mechanism (R01). Planning, direction, and execution of the proposed project will be solely the responsibility of the applicant. The RFA is a one-time solicitation. The total project period for applications submitted in response to this RFA may not exceed five years; continuation of each awarded project will depend on an annual progress review and availability of funds.

FUNDS AVAILABLE

AHCPR expects to commit up to \$3 million for six to ten competitive awards under this RFA. The issuance of awards will be contingent on the availability of funds and the quality of the applications.

RESEARCH OBJECTIVES

The enabling legislation for the AHCPR (P.L. 101-239) authorizes the study of the appropriateness and effectiveness of the use of services and procedures in the prevention, diagnosis, treatment, and management of clinical conditions. The law recognizes drug therapy as an important form of treatment and refers specifically to the need to investigate the appropriate use of prescription drugs. The purpose of this RFA is to encourage studies on the outcomes of pharmaceutical therapy.

This RFA emphasizes the relationship between prescription drugs, related services, and patient outcomes in ambulatory care settings. Of particular importance is the need to increase the availability and use of data and empirical methods in research on the patient outcomes of pharmaceutical therapy.

Three general areas of research are of interest:

- o data and analytic methods;
- o factors affecting the appropriateness of drug prescribing; and
- o the role of the patient.

Described below, the issues and questions raised are illustrative only, and other study topics relevant to this RFA are welcome.

Data and Analytic Methods

There is a critical need for comprehensive, comparative assessment of the appropriateness and effectiveness of alternative pharmaceutical therapies. Researchers should consider using existing data collected for either administrative or research purposes. These sources can be supplemented with primary data collection. Emphasis is to be given to the study of clinical conditions that meet the following criteria:

- o the predominant mode of therapy is pharmaceutical;
- o a large number of patients are affected;
- o the use of health care resources is substantial; and
- o a variety of therapeutic choices exist.

The AHCPR encourages studies of the following:

- o What is the feasibility of using and/or developing comprehensive databases to address questions concerning the outcomes of pharmaceutical treatment?
- o Accurate ascertainment of drug exposure is essential. How valid are currently used measures of drug exposure?
- o How can the association between pharmaceutical treatment to achieve surrogate endpoints and patient outcomes be validated?
- o Comparative cost-effectiveness studies that can be used by the industry and research community as models or standards for analysis would be especially useful.
- o What hypotheses on the outcomes of pharmaceutical therapy can be tested using international sources of data?

Factors Affecting the Appropriateness of Drug Prescribing

Previous studies have explored the effects of policy and educational interventions on drug prescribing. Many questions remain about the long-term effects of private and public programs that monitor and intervene in the prescribing process. The AHCPR is interested in research on the effects on patient outcomes of programs designed to improve the appropriateness of drug prescribing.

The AHCPR encourages studies of the following:

- o Of particular interest to this RFA are questions dealing with the link between drug utilization review (DUR) and patient outcomes in Medicaid or other programs in the ambulatory care setting.
- o Evaluative questions regarding the relationship of pharmaceutical care, specifically pharmacists' cognitive services, and patient outcomes are encouraged.
- o Interventions to change prescribing behavior range from academic detailing to less costly computer-generated letters. Further study of the effects of these interventions on prescribing behavior and on patient outcomes is needed.

The Role of the Patient

Therapeutic goals are condition- and patient-specific, and desired outcomes will vary by disease, severity of illness, consequences of therapy, and associated treatment costs. In addition to objectively measured consequences of treatment, outcomes of importance include subjective measures of patients' quality of life, satisfaction, and perceived functional status.

The AHCPR is interested in studies that will address the following:

- o How does patient compliance with a drug regimen vary with respect to changes in quality of life and functional status?
- o What is the association between objective and subjective measures for specific conditions?
- o To what extent can existing databases, or new primary data collection, be used to examine the relationship between self-care and patient outcomes?
- o How can existing models and instruments measuring patient satisfaction, quality of life, functional status, and utility be used to compare outcomes among alternative therapies?

SPECIAL REQUIREMENTS

Applications should specifically address the appropriateness and/or effectiveness of pharmaceuticals or related services. Projects should include investigator(s) and key staff who reflect the multidisciplinary nature of outcomes research.

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN STUDY POPULATIONS

The AHCPR adheres to NIH and ADAMHA policy that requires applicants for research grants and cooperative agreements to include minorities and women in study populations. If minorities or women are excluded or inadequately represented in proposed research, a clear and compelling rationale must be provided. The application must reflect this policy, or it will be returned without review.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev.9/91) is to be used in applying for these grants. State and local government agencies may use form PHS 5161. These forms are available from: Office of Scientific Review, Agency for Health Care Policy and Research, 2101 East Jefferson Street, Suite 602, Rockville, MD, 20852, telephone: (301) 227-8449.

The RFA contains further details regarding the application procedures. Applications must be received by July 15, 1992.

CONFERENCE FOR PROSPECTIVE APPLICANTS

The AHCPR plans to convene a conference in Chicago on April 30, 1992, prior to the application receipt date. Attendance is not a prerequisite for applying. All personal travel costs and accommodations are the responsibility of the attendees. Individuals with questions concerning this announcement, or unable to attend the conference, may call or write the AHCPR staff members listed below for further technical and/or administrative assistance.

REVIEW PROCEDURES

Upon receipt, applications will be reviewed by AHCPR staff for completeness and responsiveness. All responsive applications will undergo initial peer review for scientific merit by an AHCPR chartered review committee of non-Federal experts. Applications that are recommended for further consideration for funding and that request total direct costs in excess of \$250,000 will be reviewed by the National Advisory Council for Health Care Policy, Research, and Evaluation.

Initial peer review will take into account the following review criteria:

- o significance and originality of goals;
- o adequacy of methodology proposed to carry out the project;
- o availability of data or proposed plan to collect data;
- o adequacy of plans for organization and implementation;
- o qualifications of the Principal Investigator and staff;
- o reasonableness of the proposed budget in relation to the project;
- o adequacy of facilities and resources available; and
- o adequacy of the proposed means for protecting against or minimizing adverse effects of project-related activities upon humans, animals, or the environment.

The RFA contains additional information regarding the review procedures and criteria.

INQUIRIES

Written and telephone requests for and inquiries concerning this RFA are encouraged.

Direct inquiries regarding programmatic issues to:

Lynn Bosco, M.D. or Eleanor M. Perfetto, Ph.D.
Center for Medical Effectiveness Research
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 605
Rockville, MD 20852
Telephone: (301) 227-8485

Direct inquiries regarding administrative and budgetary matters to:

Ralph L. Sloat
Chief, Grants Management Branch
Office of Planning and Resource Management
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 601
Rockville, MD 20852
Telephone: (301) 227-8447

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.180. Awards are made under authority of Title IX of the Public Health Service Act (42 U.S.C. 299-299c-6) and section 1142 of the Social Security Act (42 U.S.C. 1320b-12); and administered in accordance with PHS grants policies, program regulations (42 CFR, Part 67, Subpart A), and other applicable Department regulations. The requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs," are not applicable to AHCPR research grant programs.

PERIODONTAL DISEASES RESEARCH CENTERS

NIH GUIDE, Volume 21, Number 12, March 27, 1992

RFA AVAILABLE: DE-92-03

P.T. 04; K.W. 0715157, 0765033, 0755030, 0785055, 0745020, 0745027

National Institute of Dental Research

Letter of Intent Receipt Date: August 17, 1992
Application Receipt Date: September 16, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The National Institute of Dental Research (NIDR) invites applications for support of categorical Periodontal Diseases Research Centers to conduct multidisciplinary research on the etiology, epidemiology, prevention, risk assessment and diagnosis, pathogenesis, and treatment of the periodontal diseases.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Periodontal Diseases Research Centers, is related to the priority area of improving oral health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by United States non-profit, public and private organizations, such as dental and medical schools, universities and research institutions. Applications from foreign institutions are not eligible.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health specialized center grant (P50). Awards will be made for five years and the earliest funding date is August 1, 1993. This RFA is a one-time solicitation; issuance of a subsequent request for new and competing continuation applications is dependent on program needs and the availability of funds. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant institution.

FUNDS AVAILABLE

The NIDR expects that \$2.5 million in total costs will be available to fund grant applications submitted in response to this RFA. If a sufficient number of highly meritorious applications are received, it is anticipated that two or three awards will be made. However, none will exceed \$500,000 in direct costs for the first year. Where indirect costs are assigned to a subcontract and counted as direct costs on the parent grant, the allowable direct cost may be exceeded by the amount of the indirect costs assigned to the subcontract.

RESEARCH OBJECTIVES

The primary objective of the Periodontal Diseases Research Centers program is to support multidisciplinary basic and clinical research that combines existing research knowledge with new innovative approaches, ultimately leading to the prevention and control of the periodontal diseases. Research areas that may be particularly appropriate for inclusion in the application for support are cited in the RFA. However, no priorities are implied and the examples should not constrain applicants from proposing other research topics or investigative approaches.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

The NIH policy is that applicants for NIH clinical research grants will be required to include minorities and women in study populations. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by August 17, 1992, a letter of intent that includes a descriptive title of the proposed center, the name, address and telephone number of the center director, the identities of other key personnel and the number and title of this RFA. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIDR staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be addressed to:

Matthew Kinnard, Ph.D.
Acting Director, Periodontal Diseases Program
Extramural Program
National Institute of Dental Research
Westwood Building, Room 509
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7784

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892; and from the program administrator named above.

Applications must be received by September 16, 1992. If an application is received after that date, it will be returned to the applicant.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed initially by NIDR staff for completeness and responsiveness. Subsequently, they will be evaluated by a special review committee convened by the Scientific Review Office, NIDR, for technical and scientific merit. Applications may be subjected to triage by the review committee to determine the scientific merit relative to other applications received in response to this RFA. The NIDR will withdraw from further competition those applications judged by triage to be noncompetitive for award and notify the applicant and institutional official. Applications judged to be competitive will undergo further scientific merit review. This review may involve an applicant interview or site visit. The second level of review will be provided by the National Advisory Dental Research Council.

Major factors to be considered in the evaluation of applications are detailed in the RFA.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged in order to clarify any issues or questions from potential applicants. Direct requests for the RFA and inquiries regarding programmatic issues to Dr. Matthew Kinnard at the address under LETTER OF INTENT.

Direct inquiries concerning fiscal matters to:

Theresa Ringler
Grants Management Officer
Extramural Program
National Institute of Dental Research
Westwood Building, Room 518
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7437

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.121. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

5-A-DAY FOR BETTER HEALTH

NIH GUIDE, Volume 21, Number 12, March 27, 1992

RFA AVAILABLE: CA-92-17

P.T. 34; K.W. 0710095, 0715035, 0404000, 1010013

National Cancer Institute

Letter of Intent Receipt Date: April 24, 1992
Application Receipt Date: June 9, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The Division of Cancer Prevention and Control of the National Cancer Institute (NCI) invites applications for grants to develop, implement, and evaluate interventions in specific community channels and/or for specific target

populations to increase the consumption of fruits and vegetables, using the 5-A-Day message. The 5-A-Day message is "Eat 5 servings of fruits and vegetables a day for better health." (Products promotable through the program and serving sizes are defined in Appendix A; available from the NCI program contact listed under INQUIRIES.) Fruits and vegetables are promoted in the program in a manner that retains their integrity as low-fat foods and as part of an overall healthy eating pattern that is low in fat and high in fiber.

A channel is defined for this application as a specific means or route for reaching consumers with messages and/or food for the purpose of creating the desired dietary behavior change. Examples are schools, food service (may include restaurants, and cafeterias) worksites, and food assistance programs. Within the channel, a target population must be selected. For example, if schools are selected as the channel, all students may be targeted or students in specific grades may be targeted.

Whenever it seems appropriate, applicants will be expected to utilize the mass media as a part of the intervention. In addition, complementary partnerships with the fruit and vegetable industry are encouraged.

The intent of the announcement is two-fold: (1) to encourage research in the development of effective community level interventions for changing dietary patterns, using a simple, positive, actionable message; and (2) to develop the community-level component of the national 5-A-Day program, providing the complementary and necessary interactive and environmental elements of successful behavioral change interventions, such as skills development, local media placement, social support, and modifications of foods offered in local food systems.

These community interventions are an important component of the larger national program, that will provide national media coverage and industry-initiated activities. The national program is a partnership between the fruit and vegetable industry and the NCI, discussed below, in the section entitled "Background" in the RFA.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, 5-A-Day for Better Health, is related to the priority area of nutrition, specifically objective 2.6. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as units of State and local governments, universities, colleges, hospitals, research institutions, consultant firms, or combinations thereof. Universities, colleges, research institutions, hospitals, and consultant firms must involve either a public health agency or some other public agency with a mandate to protect public health and the ability to access and intervene appropriately in the channel or community chosen. All applications will be expected to incorporate appropriate research design and analysis expertise, most frequently provided by universities, colleges, research institutions, and consultants. Interdisciplinary teams of applicants are encouraged. Among a team of applicants, one institution must be proposed as the lead institution. Foreign applicants are not eligible. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. However, it is anticipated that a network of grantees will be formed to share design and evaluation strategies, compare results whenever possible, and distill lessons learned from all grants combined. (See SPECIAL REQUIREMENTS section.) The total project period for applications submitted in response to the present RFA may not exceed four years.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

FUNDS AVAILABLE

The NCI anticipates that \$4,000,000 in total costs per year for four years will be available for this RFA. Up to 10 awards are planned. This funding level is contingent upon receipt of a sufficient number of applications of high scientific merit and availability of funds. The total project period for each award will be up to four years. Applicants should determine what resources are required to achieve their scientific objectives and budget accordingly.

RESEARCH OBJECTIVES

The goal of this research is to develop, implement and evaluate interventions in specific community channels and/or for specific target populations to increase the consumption of fruits and vegetables using the 5-A-Day message.

The primary objectives of this research are:

- (1) To increase awareness in the target population of the importance of eating at least five servings of fruits and vegetables every day for better health.
- (2) In channels chosen, whenever appropriate, to increase the supportiveness of the environment for increased fruit and vegetable consumption, either through increasing the offering of foods that meet the criteria for the 5-A-Day program, policy changes, or other structural or educational changes that would promote fruit and vegetable

consumption. (Criteria are listed in Appendix A of the RFA.)

(3) To increase the daily consumption of fruits and vegetables in the target population significantly more than in the control population.

Applications must address one of the following two design options. Designs other than those described below are allowed but will require justification:

(1) Interventions focused on a specific channel:

The major research question to be answered is: Will the target groups (e.g., schools, worksites) in a specific channel receiving a 5-A-Day intervention, based on a selected model of dietary behavior change, demonstrate a significantly greater increase in fruit and vegetable consumption than the groups in the same channel not receiving the intervention? (The unit of randomization is most likely to be a group. See the section on sample size considerations in the RFA.) Other research questions of interest are: Will the target groups in a specific channel receiving a 5-A-Day intervention demonstrate greater changes in dietary awareness, knowledge, attitudes, and behavior than the control groups? Will the organizations or entities in a specific channel receiving a 5-A-Day intervention (e.g., schools, school cafeterias, worksites, worksite cafeterias) demonstrate greater environmental support for increased fruit and vegetable consumption than the organizations or entities in the same channel not receiving the intervention? Other innovative research questions are invited.

(2) Interventions focused on a specific hard-to-reach population:

The major research question to be answered is: Will the groups in a specific hard-to-reach population receiving a 5-A-Day intervention, based on a selected model of behavioral change, demonstrate a significantly greater increase in fruit and vegetable consumption than groups in the same target population, not receiving the intervention? Choice of a single channel is preferable for this research question. However, more than one channel may be used with adequate justification of the specific channels as more appropriate for reaching the target population than a single channel. Examples of appropriate target populations might be ethnic groups, such as Blacks, Hispanics, and Asians, low income groups, low literacy groups, and groups at high risk. Other research questions of interest are the same as those enumerated in design option (1) above, applied to the hard-to-reach target population. Other innovative research questions are invited.

SPECIAL REQUIREMENTS

Networking among investigators will be expected. Thus, each grantee should include in her/his budget enough funds for at least two investigators to attend two meetings per year in Washington DC with fellow grantees.

Investigators will be expected to supply a final report in a specific format that summarizes both successes and failures to contribute to the dissemination of community intervention research. In addition, grantees will be expected to participate in a joint summary of results of all grants. Grantees will be licensed to use the 5-A-Day logo.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 24, 1992, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIH staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Jerianne Heimendinger, Sc.D., M.P.H., R.D.
National Cancer Institute
Division of Cancer Prevention and Control
Executive Plaza North, Room 330
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-8520
FAX: (301) 402-0816

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/496-7441; and from the NIH program administrator named in INQUIRIES below.

Applications must be received by close of business, June 9, 1992. If the application is received after that date, it will be returned to the applicant.

REVIEW CONSIDERATIONS

Upon receipt applications will be reviewed by NCI staff for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NCI staff will contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next review cycle.

Those applications that are complete and responsive will be evaluated for scientific/technical merit by an appropriate peer review group convened by the NCI. The second level of review will be provided by the National Cancer Advisory Board.

The review group will recommend an appropriate budget and period of support for each application that is recommended for further consideration.

INQUIRIES

Written and telephone requests for and inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Jerianne Heimendinger, Sc.D., M.P.H., R.D.
National Cancer Institute
Division of Cancer Prevention and Control
Executive Plaza North, Room 330
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-8520
FAX: (301) 402-0816



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Direct inquiries regarding fiscal matters to:

Catherine Blount
National Cancer Institute
Grants Administration Branch
Grants Management Section
Executive Plaza South, Room 243N
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-7800

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

**THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:

5333 Westbard Avenue
Bethesda, MD 20816

NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21., No. 12, Part II of II
March 27, 1992

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National Institutes of Health

ONGOING PROGRAM ANNOUNCEMENTS

NATIONAL DIGITAL MAMMOGRAPHY DEVELOPMENT GROUP (PA-92-57)

National Cancer Institute

INDEX: CANCER

CLINICAL RESEARCH ON HUMAN DEVELOPMENT AND DRUG ABUSE (PA-92-58)

National Institute on Drug Abuse

INDEX: DRUG ABUSE

GENOME INFORMATICS PROGRAM (PA-92-59)

National Center for Human Genome Research

INDEX: HUMAN GENOME RESEARCH

PREVENTION OF INSULIN DEPENDENT DIABETES MELLITUS BY IMMUNOMODULATION (PA-92-60)

National Institute of Diabetes and Digestive and Kidney Diseases

National Institute of Allergy and Infectious Diseases

National Institute of Child Health and Human Development

INDEX: DIABETES, DIGESTIVE, KIDNEY DISEASES; ALLERGY, INFECTIOUS DISEASES; CHILD HEALTH, HUMAN DEVELOPMENT

CANCER PREVENTION AND CONTROL RESEARCH (PA-92-61)

National Cancer Institute

INDEX: CANCER

CAUSES AND EFFECTS OF ELDERLY POPULATION CONCENTRATIONS (PA-92-62)

National Institute on Aging

Agency for Health Care Policy and Research

INDEX: AGING; HEALTH CARE POLICY RESEARCH

CHEMISTRY-BIOLOGY INTERFACE PREDCTORAL TRAINING (PA-92-63)

National Institute of General Medical Sciences

INDEX: GENERAL MEDICAL SCIENCES

RESEARCH ON HERITABLE DISORDERS OF CONNECTIVE TISSUE (PA-92-64)

National Institute of Arthritis and Musculoskeletal and Skin Diseases

National Institute of Child Health and Human Development

INDEX: ARTHRITIS, MUSCULOSKELETAL, SKIN DISEASES; CHILD HEALTH, HUMAN DEVELOPMENT

ERRATUM

BI-COMPARTMENT TRANSDERMAL CONTRACEPTIVE DELIVERY SYSTEM (RFP NICHD-CD-92-12)

National Institute of Child Health and Human Development

INDEX: CHILD HEALTH, HUMAN DEVELOPMENT

This publication is also available electronically to institutions via BITNET or INTERNET. Alternative access is through the NIH Grant Line using a personal computer. Contact Dr. John James at 301/496-7554 for details, or send an E-mail message to ZNS@NIHCU.

ONGOING PROGRAM ANNOUNCEMENTS

NATIONAL DIGITAL MAMMOGRAPHY DEVELOPMENT GROUP

NIH GUIDE, Volume 21, Number 12, March 27, 1992

PA NUMBER: PA-92-57

P.T. 34; K.W.0715035, 0745020, 0706030, 1004000

National Cancer Institute

PURPOSE

The National Cancer Institute (NCI) through the Diagnostic Imaging Research Branch (DIRB) of the Radiation Research Program seeks grant applications through Interactive Research Project Grants (IRPGs) in order to form a National Digital Mammography Development Group (NDMDG) that will consist of six major components: (1) software and hardware for digital mammography; (2) image processing; (3) computer-aided diagnosis; (4) telemammography; (5) pre-clinical and clinical technology evaluation; and (6) Headquarters for the scientific leadership (development of experimental design and data processing). The objective of this program announcement (PA) is to establish a multi-institutional, multi-disciplinary scientific group to facilitate integrated development and evaluation of digital mammography and related technologies, such as image processing, computer-aided diagnosis (CAD), and telemammography, for improved breast cancer imaging and characterization.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, National Digital Mammography Development Group, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit, public and private organizations, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This program will be supported through the research project grant (R01) mechanism. The NCI encourages the coordinated submission of related research project grant applications from investigators who want to collaborate on a common cancer research theme but do not require extensive shared physical resources or core functions. A minimum of three independent investigators with related research objectives are encouraged to submit concurrent, collaborative, cross-referenced individual research project grant applications (R01) that share a common research focus. Applications may be from either a single institution or a consortium of institutions. Applications will be reviewed independently for scientific merit. Meritorious applications will be considered for funding both as independent awards and in the context of the overall proposed collaboration.

Applicants will be responsible for the planning, direction, and execution of the proposed projects. One Principal Investigator out of the group MUST be identified as the "Program Coordinator," and must be cited in all applications on page 2 of form PHS 398. Individual investigators may request funds for the time and effort contributed toward the coordination of the overall research and for collaborative resource activities.

Additional information about the interactive R01 mechanism may be found in the NIH Guide for Grants and Contracts, January 10, 1992, in Interactive Research Project Grants for Cancer, PA-92-29."

Awards will be administered in accordance with Public Health Service Policy as described in the PHS Grant Policy Statement, DHHS. Publication No. (OASH) 90-50,000 revised October 1, 1990.

RESEARCH OBJECTIVES

Background Information

The goal of this announcement is to stimulate research in the area of digital mammography and related technologies to improve breast cancer detection and staging. The scope of the proposed research will encompass technologic developments in digital mammography integrated with basic research in critical avenues that can be opened by digital mammography, such as image processing for improved lesion visualization, computer-aided diagnosis (CAD) for enhanced image interpretation and teleradiology, or electronic image transmission, as a potential mechanism to bring world expertise to community hospitals. To achieve the above-stated goals, the NDMDG will be established to ensure comprehensive collaboration among industry (e.g., design of receptor or display systems), the academic community, and the NCI for an integrated, multi-component approach to digital mammography development. The NDMDG will be supported by the interactive program by using the R01 funding mechanism (as described in the NIH Guide for Grants and Contracts, January 10, 1992) and will consist of six major components: (1) digital mammography; (2) image processing; (3) CAD; (4) teleradiology; (5) pre-clinical and clinical technology evaluation; and (6) Headquarters for the scientific leadership (centralized development of experimental design and data processing).

Research Goals and Scope

The major thrust of this initiative is to facilitate integrated technologic development of digital mammographic systems. This PA encompasses a full range of studies from basic technology and instrumentation development through pre-clinical and clinical evaluation. The research agenda for the NDMDG encompasses the following goals:

- o To develop and evaluate new technologic advances to increase image quality in digital mammography (e.g., spatial/contrast/time resolution);
- o To develop and validate new digital imaging methodology (dynamic or "real time" imaging);
- o To develop and validate new image processing techniques to increase the sensitivity of the detection of lesions;
- o To develop and validate new algorithms, neural networks, and other forms of machine intelligence for CAD; and
- o To develop and validate practical methods of data compression, storage, and image transmission for telemammography.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit

to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The following is a statement of NIH and ADAMHA policy regarding the inclusion of women and minorities in study populations. Applications that are responsive to this PA will, by definition, meet the requirement for inclusion of women. However, the inclusion of racial and ethnic minorities must be addressed in applications submitted responding to this PA.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Section 2, 1-4 of the Research Plan AND summarized in Section 2, E, Human Subjects.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans [including American Indians or Alaskan Natives], Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including not but limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned. Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for this program announcement. These forms are available at most institutional business offices, from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892, telephone (301) 496-7441, and from the NCI program director named below.

The PA number and title must be typed on line 2a of the face page of the application form.

The use of the IRPG mechanism must be mentioned briefly in form PHS 398, Sections 1-4 of the Research plan. The goal of the collaborative efforts MUST be identified in the specific aims of each application, with the major rationale and explanation for the use of the IRPG mechanism to be given in Section G, Consultants/ Collaborators. A complete list of applications in the IRPG must be provided in Section G, and an indication of the specific collaborations to be established for the individual application under consideration.

Requests for limited shared resources, if any, must be proportionally budgeted in each application based on anticipated use, with a full explanation given in the budget. Personnel Time and Effort requests for management of shared resources are allowable. If consortium arrangements between independent institutions are proposed that would make transfer of funds for required new equipment impractical, the entire equipment request may be budgeted by the responsible laboratory. This must be clearly justified.

All PHS and NIH grants policies will apply to applications received in response to this announcement.

If the applicant has an approved assurance covering the research (multiple project assurance for human subjects/full assurance of compliance for animal subjects), the applicant should provide with the application certification of institutional review board (IRB) approval if humans are involved and verification of the institutional animal care and use committee (IACUC) approval if animals are involved. These reviews and approvals should occur PRIOR TO SUBMISSION of the applications and the certifications and verifications should be SUBMITTED WITH the applications. If animals or humans will be subjects of research at PERFORMANCE SITES OTHER THAN THE APPLICANT ORGANIZATION, the applicants must identify, with the application, the assurance status of each participant.

Submit a signed, typewritten original of the application, including the Checklist, and five signed, exact photocopies, in one package to the address below. The photocopies must be clear and single sided.

DIVISION OF RESEARCH GRANTS
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of this PA and inquiries about whether or not specific proposed research would be responsive are encouraged and are to be directed to:

Faina Shtern, M.D.
Chief, Diagnostic Imaging Research Branch
Radiation Research Program
National Cancer Institute
Executive Plaza North, Suite 800
Bethesda, MD 20892
Telephone: (301) 496-9531

Dr. Shtern welcomes the opportunity to clarify any issues or questions from potential applicants.

Direct inquiries regarding programmatic issues to:

Joan Metcalfe
Grants Management Specialist
National Cancer Institute
Executive Plaza South, Room 242
Bethesda, MD 20892
Telephone: (301) 496-7800, extension 28

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.395, Cancer Treatment Research. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

CLINICAL RESEARCH ON HUMAN DEVELOPMENT AND DRUG ABUSE

NIH GUIDE, Volume 21, Number 12, March 27, 1992

PA AVAILABLE: PA-92-58

P.T. 34; K.W. 0404009, 0775000, 0775025, 0755020

National Institute on Drug Abuse

PURPOSE

The National Institute on Drug Abuse announces the availability of a program announcement on the above subject. The purpose of this announcement is to stimulate clinically relevant research to improve the ability to identify, measure, intervene, track, and prevent dysfunctional human development resulting from prenatal exposure to drugs, environmental exposure to drugs, growing up in a drug abusing environment, child abuse and neglect by drug abusing care providers, and related factors associated with developmental and intergenerational patterns of drug abuse and transmission of AIDS. Research studies using animal models to investigate clinical questions are included as are studies of clinical and legal issues related to drug screening, risk assessment, parent and child rights, drug treatment, child custody, and interventions for the child.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) urges applicants to submit applications that address specific objectives of "Healthy People 2000." Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0; or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by public and private, non-profit and for-profit organizations such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Women and minority investigators are encouraged to apply. Individual fellowship applicants must be citizens or noncitizen nationals of the United States for permanent residence and have in their possession an Alien Registration Receipt Card (I-151 or I-155) at the time of application. Individuals on temporary or student visas are not eligible. See National Research Service Awards for Individual Postdoctoral Fellows, October 1990, for additional information, available from the contact listed under INQUIRIES.

RESEARCH OBJECTIVES

In 1989, national random surveys and clinical studies indicated that approximately 11 percent of pregnant women abused drugs during pregnancy. Considering that the average drug abusing career lasts 14 years with onset in early adolescence, one in ten children (one in five children in urban poverty areas) may be reared by a careprovider who abuses or is addicted to illicit substances. In random drug screening in two children's hospitals, between 8 and 20 percent of infants and young children tested positive for cocaine with some children presenting with convulsions or seizures. Clinical studies reveal both highly specific and global developmental effects--or no effects--from pre- and postnatal exposure to drugs.

More research is needed on the assessment procedures and to explore the relationship between stage and rate of development and effects of drug exposure. Research is needed on the stages of development, vulnerabilities at each stage, possible interventions at each stage, effects of physiologic, affective, cognitive, and social development that sets the basis for subsequent development, and possible prevention strategies to prevent dysfunctional effects and further drug exposure and risk of drug use by the developing child and adolescent. Also of concern is the impact of child abuse and neglect by drug abusing care providers (mother, father, and household members) in the etiology of developmental and psychiatric disorders associated with subsequent drug use. Disorders include developmental psychopathologies, behavioral and learning problems, deficits, and mental disorders such as post traumatic stress and affective and personality disorders. Applicants are encouraged to utilize a family model and consider multi-generational, environmental and cultural factors.

Because of the impact of legal issues and health policy on drug screening, parent and child rights, child custody, protective services, and drug treatment, these legal and policy areas are an integral part of this area of research.

Studies involving animal models are also needed to address questions that cannot be addressed with human subjects.

INCLUSION OF WOMEN AND MINORITIES

Applications are required to include women and minorities in study populations for clinical research, unless compelling scientific or other justification for not including either women or minorities is provided. Applications will be reviewed for compliance with the relevant policies, and the potential applicant should carefully read the section on women and minorities in the full announcement.

MECHANISMS OF SUPPORT

Support mechanisms include Research Projects (R01), Small Grants (R03), Conference Grants (R13), First Independent Research Support and Transitional Awards (R29), Predoctoral and Postdoctoral Individual National Research Service Awards (F31 and F32), Institutional National Research Service Awards (T32), and Research Scientist Development Awards (K20 and K21).

APPLICATION PROCEDURES

Applicants for research grants are to use the application form PHS 398 (rev. 9/91). The title and number of this announcement must be typed in item number 2a of the face page of the PHS 398 application form. Applicants for individual fellowships must use form PHS 416-1 (rev. 7/88).

Application kits containing the necessary forms and instructions may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following office may be contacted for the necessary application material. The signed original and five permanent legible copies of the completed PHS 398 application must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applications using the PHS 416-1 must submit the original and two copies.

Receipt dates for R01, R03, R13, R29, K20, and K21 are February 1, June 1, and October 1. The single receipt date for T32s is May 10, F31 and F32 receipt dates are January 10, May 10, and September 10.

REVIEW CONSIDERATIONS

The Division of Research Grants, NIH, serves as a central point for receipt of applications. Applications received under this announcement will be assigned to an initial review group (IRG) for scientific review in accordance with established Public Health Service Referral Guidelines. The IRGs consist primarily of non-Federal experts. Notification of the review outcome will be sent to the applicant after the initial review.

Applications will receive a secondary review for policy considerations by the appropriate National Advisory

Council. Only applications recommended for further consideration by Council may be considered for funding. Individual fellowships, receive a secondary review by the staff of the appropriate institute.

Review Criteria

Criteria for scientific/technical merit review of applications will include the following: significance and originality from a scientific or technical standpoint of the goals of the proposed research; adequacy of the research methodology proposed to carry out the study; feasibility of the proposed research; qualifications and research experience of the Principal Investigator and other key research personnel; availability of adequate facilities, other resources, and collaborative arrangements necessary for the research; appropriateness of budget estimates for the proposed research activities; and adequacy of provisions for the protection of human and animal subjects.

For individual fellowships, major considerations in the review are the applicant's potential for a productive scientific career, the need for the proposed training requested, and the possibility that the research training proposal will meet that need. The program announcement contains additional details.

INQUIRIES

Further information and consultation on program requirements relevant to this announcement may be obtained from:

Dr. Coryl Jones
Epidemiologic Research Branch
Division of Epidemiology and Prevention Research
National Institute on Drug Abuse
Rockwall II Building, Suite 615
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-1514

A complete copy of the program announcement and information on fiscal or grants management issues may be obtained from:

Grants Management Branch
National Institute on Drug Abuse
Parklawn Building, Room 8A-54
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-6710

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.277, 93.278 and 93.279. Grants will be awarded under the authority of sections 301 and 515 of the Public Health Service Act, (42 U.S.C. 241 and 290cc) and administered in accordance with the PHS Grants Policy Statement and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health System Agency review.

GENOME INFORMATICS PROGRAM

NIH GUIDE, Volume 21, Number 11, March 20, 1992

PA NUMBER: PA-92-59

P.T. 34; K.W. 1215018, 1004017, 0780018

National Center for Human Genome Research

PURPOSE

The National Center for Human Genome Research (NCHGR) is interested in facilitating research and development in computational and information science that will support the achievement of the goals of the Human Genome Project. This announcement contains a description of the current priority areas of informatics research for the Human Genome Project and solicits applications for the Genome Informatics Program. It is anticipated that the Genome Informatics Program will support informatics research in selected targeted areas and will support establishment and operation of data repositories required to collect the results of the Human Genome Project and to make those results available to the broader biomedical research community.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged.

MECHANISMS OF SUPPORT

The support mechanisms used to support research, development, and infrastructure projects in the Genome Informatics Program are research grants (R01), program project grants (P01), pilot projects and feasibility studies (R21), and First Independent Research Support and Transition (FIRST) awards (R29). In addition, applications for research in genome informatics are also solicited by the following program announcements:

- o PA-91-88 "Courses Related to Genomic Analysis" mechanism: T15 Continuing Education Training Grants;
- o PA-91-89 "Special Emphasis Research Career Award in Genomic Research" mechanism: K01 Special Emphasis Research Career Award (SERCA);
- o PA-92-22 "National Research Service Awards in Genomic Analysis" mechanisms: T32 Institutional Predoctoral Research Training Programs; F32 Individual Postdoctoral Fellowships; F33 Senior Postdoctoral Fellowships; and
- o PHS 91-2 "Omnibus Solicitation of the Public Health Service for Small Business Innovation Research (SBIR) Grant Applications" mechanisms: R43 Phase I SBIR Grants; R44 Phase II SBIR Grants.

These program announcements are available from the National Center for Human Genome Research at the address below. Applicants are encouraged to contact NCHGR staff to discuss the appropriateness of a particular support mechanism and any special application requirements.

RESEARCH OBJECTIVES

The primary purposes of Genome Informatics Program are to develop new technology needed to accomplish the objectives of the Human Genome Project and to apply these technologies to the acquisition, management, analysis, and dissemination of mapping and sequencing information. Each project must have tangible and, whenever possible, quantifiable aims that define a specific objective that the project intends to accomplish during the granting period. The project will be accountable for the attainment of such milestones through yearly progress reports, timely publication and dissemination of results including software and database designs and source code, and the competitive renewal process.

The specific objectives appropriate to Genome Informatics Program grants are:

- o Development of laboratory data management systems tailored to large-scale genome mapping and sequencing projects;
- o Development of new and improved algorithms for analysis of experimental mapping or sequencing data, especially with the aim of generating consensus genetic or physical maps or finished sequence;
- o Development of new and improved algorithms for analysis and display of consensus (or finished) genomic mapping or sequencing data;
- o Development of prototype database designs and implementations to test novel approaches to representation of genomic mapping and sequencing data;
- o Implementation of the algorithms described above in efficient, well-documented, and tested programs; and
- o Development of shared data resources or repositories for data generated by the Human Genome Project.

This list should be considered illustrative and not exclusive.

It is anticipated that, to the maximum extent possible, research and development projects will be carried out with the active participation of the biological scientists who will be the data generators and users and the ultimate users of the tools and databases developed under this program.

Where appropriate, collaboration with industry is encouraged. In such a collaboration, the industrial contribution must be well integrated into the design and operation of the project to encourage cross-fertilization of ideas and rapid application of the research to practical purposes.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit.

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441. The title and number of the announcement must be typed in Section 2a on the face page of the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH or by an appropriate Institute or Center review group in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council. Review criteria that will be used by the initial review group to assess the scientific merit are: (1) Significance and originality of the research and methodological approaches; (2) Feasibility of the research and adequacy of the experimental design; (3) Training, experience, research competence, and commitment of the investigator(s); (4) Adequacy of the facilities and resources; and (5) Appropriateness of the requested

budget for the work proposed.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that ICD. The following will be considered in making funding decisions: (1) Quality of the proposed project as determined by peer review; (2) Balance among research areas of this announcement; and (3) Availability of funds.

For applications assigned to the NCHGR, an additional award criterion is the value of the proposed research for achieving the goals of the National Center for Human Genome Research. In addition, because projects to develop informatics tools and databases differ significantly from typical individual research projects, appropriate award criteria will also differ depending on the nature of the work proposed. The following award criteria are provided to illustrate the mix of criteria employed in the evaluation of a particular application.

Prototype database development:

- o Adequacy, permanence, completeness, and safety of data storage;
- o Provision for integration with related databases;
- o Generality of the data structure design (e.g., species-independence) to the extent that generalizing the design does not impose unreasonable costs; and
- o Adequacy of design and system documentation and plans for its distribution.

Development of software tools:

- o Portability at the source code level;
- o Portability of the user interface;
- o Portability or general availability of required external hardware or software (e.g., graphics terminals, plotters, database managers, vector processors);
- o Adequacy of plans for distribution and appropriate support, including public domain distribution and/or commercialization;
- o Appropriateness of software engineering methodology to be employed;
- o Adequacy of design and system documentation and plans for its distribution; and
- o Adequacy of plans for development of user documentation.

Operational laboratory database implementation:

- o All the criteria listed above;
- o Adequacy of quality control, sample tracking, and overall project management;
- o Adequacy of data transfer rate (adequate for the anticipated data entry and query load);
- o Adequacy of provision for "community" access, if appropriate; and
- o Adequacy of data protection from unauthorized access or modification.

Public database implementation:

- o All the criteria listed above;
- o Provision for multiple forms of access or distribution;
- o Provision of a well-documented, clearly specified Application Program Interface (API) supporting (at a minimum) query and retrieval;
- o Provision for network accessibility through the Internet, using well-recognized standards (i.e., TCP/IP);
- o Use of a commercial database management system running on a POSIX-conforming operating system (unless justification for doing otherwise is presented);
- o Use of consistent, well-recognized standards;
- o Support for differential (among authorized users) accessibility of data; and
- o Provision for maintaining a history of changes to the database (an audit trail or set of editorial citations).

In general, other issues (e.g., hardware, operating system, database management system) will be considered only to the extent that they influence the adequacy and economy of the system evaluated according to the criteria given above.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

David Benton, Ph.D.
Director, Genome Informatics Program
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20894
Telephone: (301) 496-7531
E-mail: benton@bio.nlm.nih.gov (internal)

Direct inquiries regarding fiscal matters to:

Ms. Alice Thomas
Chief, Grants and Contracts Management Section
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20894
Telephone: (301) 402-0733

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.172. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

PREVENTION OF INSULIN DEPENDENT DIABETES MELLITUS BY IMMUNOMODULATION

NIH GUIDE, Volume 21, Number 12, March 27, 1992

PA NUMBER: PA-92-60

P.T. 34; K.W. 0715075, 0745027, 0745045

National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Allergy and Infectious Diseases
National Institute of Child Health and Human Development

PURPOSE

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institute of Allergy and Infectious Diseases (NIAID), and the National Institute of Child Health and Human Development (NICHD) are seeking applications for clinical studies designed to test the hypothesis that immunomodulation will prevent insulin-dependent diabetes mellitus (IDDM) in high-risk populations.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Clinical Trials to Prevent Insulin Dependent Diabetes Mellitus by Immunomodulation, is related to the priority area of diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by public and private, foreign and domestic, for-profit and non-profit organizations, such as universities, colleges, hospitals and laboratories, units of State and local governments, and authorized units of the Federal Government. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

The mechanism for support for this program will be the individual research grant (R01). The application may include subcontracts or consortia with several institutions. Due to fiscal constraints, the NIDDK does not anticipate being able to provide more than \$500,000 in total costs to any one application.

RESEARCH OBJECTIVES

Background

Over the past 10 years, significant progress has been made in defining the autoimmune etiology and pathophysiology of IDDM. Several clinical trials of general immunosuppressive agents in patients with newly diagnosed IDDM have induced a temporary clinical remission of this disease. These observations have led to the hypothesis that

immunomodulatory interventions may be effective in the prevention of this disease in individuals who are asymptomatic but who are in an earlier period of the autoimmune process.

A workshop on Clinical Trials of Immunosuppression for Prevention of IDDM was held on April 19-20, 1990, in Bethesda, Maryland. This workshop was sponsored by the NIDDK, NIAID, and NICHD. It was the charge of this group to assess the status of scientific and medical knowledge necessary to initiate a clinical trial of immunomodulatory intervention for the prevention of IDDM. Participants for the meeting were drawn from the diabetes and immunology research communities and were chosen to provide a broad range of insight and judgment in these areas. Several major issues were extensively discussed, and consensus was reached in some areas while others remained open for continued examination, evaluation, and debate. There was general consensus based on the published literature and discussion on the following important issues:

- o IDDM in humans is an autoimmune disease and, as such, should be amenable to immunotherapeutic intervention;
- o There are measurable parameters that can identify a group of individuals at high risk for the development of IDDM; and
- o Further clinical studies in high-risk individuals to explore the ability of immunomodulation to alter the natural history of IDDM are timely and warranted.

Concerns were expressed by several of the participants that applicants utilizing pediatric populations must strongly justify the risks and benefits to the trial participants. A summary of this workshop is available from the NIDDK staff listed under INQUIRIES.

Goal and Scope

The goal of this program announcement is to stimulate clinical research that will evaluate the effectiveness of immunomodulatory therapies for the prevention of IDDM in high-risk populations. The research scope of this program will encompass a range of basic and clinical research disciplines, such as immunology, endocrinology, genetics, biochemistry, pharmacology, physiology, and pediatrics. Some examples of relevant research areas to be addressed by these clinical studies include:

- o Identification and characterization of markers that have value in predicting remission or progression in pre-IDDM individuals on long-term immunotherapy;
- o Using presently available markers, determine the natural history of high-risk individuals; and
- o Evaluation of the effect of immunomodulatory interventions in high-risk individuals including efficacy in prevention of progression of the autoimmune process and parameters such as dosage, duration, and deleterious side effects.

These recommendations are not necessarily all inclusive and any new ideas with credible hypotheses that would appropriately fall within the scope of this announcement may be the basis for an application.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues must be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Section 2, 1-4 of the Research Plan and summarized in Section 2, E, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventative strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applicants are to use the research grant application form PHS 398 (rev. 9/91). If application kits are not available at the institution's business office or central application control office, a copy may be obtain from the Office of Research Grants, National Institutes of Health, Division of Research Grants, 5333 Westbard Avenue, Room 449, Bethesda, MD, 20892, telephone 301-496-7441.

In order to identify the application as a response to this program announcement, check "yes" on Item 2a of the application face page with the title, "Prevention of IDDM by Immunomodulation, PA-92-60."

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center of Research Resources may wish to identify the Center as a resource for conducting the proposed research. In such a case, a letter of agreement from the GCRC Program Director must be included in the application material.

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications in response to this solicitation will be reviewed in accordance with the usual NIH peer review procedures. Applications will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (study section). Secondary reviews will be by an appropriate national advisory council.

AWARD CRITERIA

Applications recommended for further consideration will compete for available funds with all other applications assigned to the Institutes. However, because the NIDDK, NICHD, and NIAID and their Advisory Councils have identified this research area to be of particular program interest, applications responsive to this announcement will be brought to the special attention of these Advisory Councils. The following will be considered in making funding decisions: quality of the proposed project as determined by peer review; availability of funds; and program balance among research areas of the announcement.

INQUIRIES

Potential applicants are encouraged to discuss their plans with any of the following NIH program staff:

Dr. Joan T. Harmon
Executive Director, Diabetes Research Program
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 622
Bethesda, MD 20892
Telephone: (301) 496-7731

Dr. Howard B. Dickler
Chief, Clinical Immunology Branch
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4A-19
Bethesda, MD 20892
Telephone: (301) 496-7104

Dr. Gilman D. Grave
Chief, Endocrinology, Nutrition and Growth Branch
National Institute of Child Health and Human Development
Executive Plaza North, Room 637
Bethesda, MD 20892
Telephone: (301) 496-5593

AUTHORITY AND REGULATION

This program is described in the Catalog of Federal Domestic Assistance No. 93.847, Diabetes, Endocrinology and Metabolism Research; 93.855, Immunology, Allergic and Immunologic Disease Research; 93.865, Research for Mothers and Children. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

CANCER PREVENTION AND CONTROL RESEARCH

NIH GUIDE, Volume 21, Number 12, March 27, 1992

PA NUMBER: PA-92-61

P.T. 34; K.W. 0715035, 0745027, 0795003, 0785055

National Cancer Institute

PURPOSE

The National Cancer Institute (NCI) invites applications for studies covering a broad range of research related to cancer prevention and control. The Division of Cancer Prevention and Control (DCPC), NCI is mandated to conduct research on cancer prevention and control and the surveillance and monitoring of the incidence, mortality, and morbidity of cancer. A priority for DCPC is to develop the means for effective translation of the knowledge gained from research in prevention and control into disease prevention and health promotion activities for the benefit of the public. The goal of these efforts is to achieve significant reductions in cancer incidence, mortality, and morbidity with a concomitant increase in cancer survival.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Cancer Prevention and Control Research, is related to priority areas of cancer, nutrition, tobacco, educational and community-based programs, clinical preventive services, and surveillance and data systems. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-011-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local government, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged.

RESEARCH OBJECTIVES

The DCPC conducts a broad array of cancer control research and application activities that emphasize validation, evaluation, and demonstration. The programs range from research on prevention, screening and early detection, to methods for applying the most effective regimens for cancer treatment, rehabilitation, and continuing care.

The primary research areas are:

- o Chemoprevention - pre-clinical and clinical studies related to the identification and evaluation of agents including nutrients that may inhibit carcinogenesis, i.e., initiation, promotion, transformation and/or progression of the malignant process as presently understood. Biomarkers or cancer occurrence may serve as endpoints.
- o Nutrition and Diet - Role of nutrients, foods or other dietary components in cancer incidence. Influence of dietary factors on the modulation of cancer risk markers, early indicators of cancer risk or intermediate endpoints. Define biochemical and molecular mechanisms by which dietary components may act as metabolic effectors that protect, control, or increase cancer risk. Absorption and metabolism of nutrients and other dietary components associated with cancer risk and prevention. Dietary assessment in human intervention trials. Development of biochemical or biological markers for dietary compliance and exposure. Improved nutritional and dietary assessment instruments including nutrient data bases. Development of reliable methods for analysis of nutrients and other components in foods, body fluids, and tissues.
- o Screening and early detection of cancer - Research to significantly reduce cancer morbidity and mortality through early detection including identification of markers of risk, exposure, and pre-malignant events of progression that can be used to identify sub-populations at particularly high risk of developing cancer. Research is also encouraged in the use of artificial intelligence for image processing as well as new imaging technologies related to early detection. Research on quality control and quality assurance related to screening and early detection is also encouraged.
- o Community Oncology - The primary objective is to stimulate research that will provide a basis to reduce the time between research advances in prevention, screening, early detection, patient management, and continuing care and the application of those advances in community settings.
- o Rehabilitation and Pain Management - Research that focuses on the application of rehabilitative medicine and pain management for cancer patients.
- o Cancer Control Applications - The development and testing of intervention strategies to modify personal, social, and lifestyle factors known to contribute to the development and/or increased risk of cancer.
- o Special Populations - Multidisciplinary intervention research aimed at addressing and modifying the excessive cancer incidence and/or mortality rates, lower cancer survival rates, or inadequate cancer prevention and control services for minority, underserved and other special populations.
- o Surveillance - Data collection, statistical analysis and mathematical modelling, health services research and information data base linkage studies are required to monitor progress toward cancer control, particularly as it pertains to national goals.

MECHANISM OF SUPPORT

The mechanism of support will be the individual research project grant (R01). Policies that govern research grant programs of the National Institutes of Health will prevail.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in the Research Plan section, 1-4, AND summarized in 5, Human Subjects. Applicants/offerees are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit.

Application kits are available at most institutional business and grant/contract offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441. The title and number of this announcement must be typed in Section 2a on the face page of the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by study sections or an ad hoc group developed by the Division of Research Grants, NIH. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that ICD. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Requests for further information may be directed to the relevant Program Director:

CHEMOPREVENTION:

Dr. Winfred Malone
Telephone: (301) 496-8567

DIET AND NUTRITION:

Dr. Carolyn Clifford
Telephone: (301) 496-8573

SCREENING AND EARLY DETECTION OF CANCER:

Dr. Barnett Kramer
Telephone: (301) 496-8544

COMMUNITY ONCOLOGY AND CONTINUING CARE:

Dr. Susan Nayfield
Telephone: (301) 496-8541

CANCER CONTROL APPLICATIONS:

Dr. Thomas Glynn
Telephone: (301) 496-8520

SPECIAL POPULATIONS:

Dr. George Alexander
Telephone: (301) 496-8589

SURVEILLANCE:

Dr. Brenda Edwards
Telephone: (301) 496-8506

All the above Program Directors are located at:

National Cancer Institute
Division of Cancer Prevention and Control
Executive Plaza North
9000 Rockville Pike
Bethesda, MD 20892-4200

Written and telephone inquiries concerning the objectives and scope of this program announcement and inquiries about whether or not specific proposed research would be responsive, clarifying scientific content and objectives of an application, size and focus of a research program, organization of an application, and appropriate use of consultants are strongly encouraged and should be directed to the relevant Program Director at the above address and telephone numbers. The Program Directors welcome the opportunity to clarify any issues or questions from potential applicants.

Direct inquiries regarding fiscal matters to:

Ms. Eileen Natoli, Team Leader, PC Team
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
6120 Executive Boulevard
Bethesda, MD 20852
Telephone: (301) 496-7800 ext. 56

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health System Agency review.

CAUSES AND EFFECTS OF ELDERLY POPULATION CONCENTRATIONS

NIH GUIDE, Volume 21, Number 12, March 27, 1992

PA NUMBER: PA-92-62

P.T. 34; K.W. 0413001, 0710010, 0408006

National Institute on Aging
Agency for Health Care Policy and Research

PURPOSE

The National Institute on Aging (NIA) and the Agency for Health Care Policy and Research (AHCPR) invite qualified researchers to submit new and supplemental applications for research projects that focus on the distribution of the elderly population across geographic areas; the factors influencing this distribution; and the social, economic and health services impacts of these distributions.

Congress, reflecting the imputed pressures on community services, housing, and health care that are associated with elderly population concentrations, has expressed interest in the NIA funding research that would "be helpful in gauging migration patterns of older Americans and in determining the impact that high concentrations of older Americans place on local service organizations and medical programs."

The spatial distribution of the American population 65 years of age and over has never been uniform; it has grown even less uniform over the past quarter-century, with a number of geographic areas, such as Florida and Arizona, accounting for both larger numbers and proportions of the elderly. These are areas of "elderly concentration." They are established cities (or subdivisions within them) and new communities; they are also smaller rural communities from which younger persons have emigrated disproportionately. (See also the *Health and Effective Functioning of Older Rural Populations*, NIA 1991.)

Migration by elderly persons, however, especially to retirement destinations, has been the primary determinant of these recent geographic concentrations. Such movements may not continue. Predicting their future pattern and volume will require understanding such influences as:

- o Selective recruitment of older persons by competing localities, including nontraditional retirement destinations. Local economic factors like housing costs and interest rates. State of national and regional economies.
- o Patterns of "continuation migration" and "reverse migration" among the older-old. Relation of socioeconomic status and other demographic characteristics to choice of destination.
- o Relative distribution of mortality improvements at the oldest ages. Changes in age, health status, and economic security at retirement.

Many data sources -- continuing national surveys, ad hoc studies at the state and local levels -- may be drawn upon. Baseline data from an important new source, the NIA funded Longitudinal Health and Retirement Study, will be available in mid-1993. It includes a 100 percent oversample of the State of Florida and is likely to be especially helpful to understanding these influences on elderly migration.

Reciprocal concerns address the changed composition of public sector budgets and a possibly diminished revenue base in areas of "elderly concentrations." Evidence from the limited research that has been conducted on these issues suggests that such concerns may be exaggerated: i.e., traditional retirement destinations, most notably those in southern and southwestern states, appear to attract populations self-selected for higher income, better health, and strong social supports. The demand for public services actually may be lower and net economic benefits higher. As these migrants age, however, pressures on community resources (e.g., public transportation, emergency medical services, home care, long-term care, and, perhaps, income support) may be expected to rise. "Reverse migration" from these centers may alter the extent -- and even the direction -- of some of these pressures. The factors influencing "reverse migration" have not been studied extensively.

Still less well researched are the dynamics and consequences of the concentration of the elderly resulting from the non-migration of aging persons who, through choice or circumstance, remain in their community and "age in place." A number of older cities, especially in the midwestern, middle Atlantic, and northeastern states, have experienced a loss of younger population of reproductive age during recent decades of economic dislocation. At the same time, improvements in mortality at more advanced ages have accounted for unprecedented survival to older age: many of these cities thus have become areas of relative elderly concentration.

Analyses of the characteristics of residents alone cannot adequately address the issues of the service demands on, or economic adjustments required of, areas with high densities of older persons. The service delivery systems in these communities, for example, not only respond to, but also shape, the demand for aging-related services. Economies of scale may be obtained in such populations, with the result that organizing and delivering commonly needed services (e.g. specialized transportation or libraries, day care or AD patients, home health assistance), will be effectively lowered. These communities of elderly concentration also afford opportunities for specialized markets and innovative services to develop, such as social HMOs or strategic interventions to avert physical disability and fiscal dependency, which may constrain costs to public and private sector budgets. The extent to which these possibilities are being realized must be studied systematically for a more rounded picture of both the determinants and the consequences of elderly population concentrations.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives

of "Healthy People 2000," a PHS-led National activity for setting priority areas. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applicants for research grants may be made by public and private, for-profit and non-profit organizations, such as universities, colleges, hospitals, or laboratories. Women and minority investigators, in particular, are encouraged to apply. Foreign institutions are welcome to apply but are advised to consult NIA or AHCPR staff before applying and are strongly encouraged to apply in collaboration with a U.S. institution.

MECHANISM OF SUPPORT

The primary mechanisms for support of this initiative are the research project grant (R01), program project grant (P01), First Independent Research Support and Transition (FIRST) Award (R29), (the AHCPR does not support the FIRST Award) conference grant (R13), individual fellowships (F32, F33).

RESEARCH OBJECTIVES

Detailed research studies on a wide range of topics are needed to expand policy-relevant knowledge on concentrated elderly populations, beginning with the analyses of recent patterns and trends of elderly migration. These will form the basis for estimating the demographic forces that will influence the extent and nature of elderly population redistribution over the next several decades. Related research projects will describe and analyze the significant influences of---and upon---ecological factors in areas of elderly concentration.

Applications proposing to address the aforementioned broad issues are encouraged, especially those that focus on specific research topics illustrated by the following examples:

A. Determinants of Elderly Population Concentration

Areas of "elderly concentration" must be defined in terms that allow spatial, demographic, and sociopolitical analysis over time. The forces by which areas become disproportionately elderly are variously categorized, and the relative role of each is likely to have a different impact on future trends.

- o What are the appropriate geographic boundaries for describing, analyzing, and comparing areas of existing elderly concentration: state, county, standard Metropolitan Area, city, subdivision? How do these alternatives accommodate research concerns for homogeneity/heterogeneity in elderly populations?
- o What are the relative contributions attributable to in-migration and to the "aging in place" of longer-term residents in specific areas with a high concentration of elderly inhabitants? Do the two populations differ in terms of socioeconomic factors, health status, patterns and intensity of health services utilization, and other factors?
- o What is the relative strength of each of the determinants for elderly migrants in choice of destination: e.g., climate, housing, employment opportunities, health care, recreation, cost of living, friendship and kinship networks? How do these differ among those who do not migrate, who "age in place," and whose communities have become areas of elderly concentration?
- o Do established communities of elderly concentration continue to attract successive cohorts of elderly migrants? Do these new migrants differ significantly from their predecessors?
- o In what ways does growth in the elderly concentration of an area correlate with change in the demographic composition of the reciprocal (i.e., non-aged) population?

B. Health Services System Adaptations

The health services systems in areas of elderly concentration are likely to reflect adaptation to the nature and needs of the population. Such adjustments may be structural or procedural, and may have statewide impacts.

- o Do elderly migrants carry private health insurance ("medigap" policies) supplementary to Medicare to the same extent, and for comparable benefit coverage, as do non-migrants? Is this coverage reflective of policies purchased before or after migration? In what ways are the premium and benefit structures different in areas of elderly concentration?
- o How do Medicaid programs of states in which areas of elderly concentration are located reflect special needs and demand for services by this population? In what ways has the entitlement/benefit/payment structure of the state Medicaid program been changed in direct response to these elderly? Have Medicaid waivers been used to provide non-traditional benefits?
- o Does the distribution of physician services---by urban/rural location, by specialty, by type of practice arrangement---reflect special accommodation to the ambulatory care needs in areas of elderly concentration? To what extent does this distribution reflect a redistribution within the state (e.g., from rural to urban, from surgery to geriatrics, from solo to group practice) or migration from other states?
- o Are age-specific and diagnosis-specific rates of hospitalization, length of stay, or hospital costs different among areas of elderly concentration, especially between populations who have migrated and those who have aged in place?
- o How does the employment/deployment of nursing personnel in areas of elderly concentration differ from that

of other areas? Are nurses working disproportionately in special hospital units, long-term care facilities, ambulatory care settings, home care agencies? Are there manifest areas of nursing shortage in the community at large that can be attributed to the elderly concentration? How do local nursing salaries respond to these shortages?

C. Environmental Adaptations

Many environmental hazards to the health and functioning of the elderly can be addressed at the community level. Do areas of elderly concentration implement such controls and, to what effect and at what cost?

o Are injuries sustained in falls actually reduced through macro-environmental interventions, e.g., in architecture, street and traffic planning? Is the social and physical mobility of frail or impaired elderly enhanced by these same interventions? Is the micro-environment of housing planned or retrofitted to reduce falls or to enhance access and mobility? Does such micro-adaptation increase or diminish the long-term real value of housing to individuals and communities?

D. Social Supports in Areas of Elderly Concentration

Social support networks generally are thought to be well established among elderly migrants at the time of their relocation.

o How do these supports (including those of adult children), and the systems of exchange and reciprocity, change for the migrant once resident in an area of "elderly concentration?" Do social support networks become narrowed to other elderly migrants and what are the consequences for health and functioning? What are the consequences for use of formal institutional or community-based services? How are crises, such as death of a spouse or of close friends, dealt with in these new support networks?

o In what way do these differ among elderly non-migrants, i.e., those who have "aged in place" and whose adult children have migrated?

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, 1-4 of the Research Plan AND summarized in Section 2, E, Human Subjects.

Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognize that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale or studies on single minority population groups should be provided.

This policy applies to all studies submitted under this program announcement. The usual NIH policies concerning research on human subjects also apply. For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the applicant, the review will be deferred until the information is provided. Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application. All applications are required to address these policies. NIH funding components will not award grants that do not comply with these policies.

REVIEW PROCEDURES

R01, R29, F32, F33, and K04 applications will be reviewed for scientific and technical merit by an appropriate Initial Review Group of the Division of Research Grants. All other applications (K01, P01, and R13) will be reviewed by an appropriate Institute review group. Secondary review will be by the corresponding National Advisory Council. Applications compete on the basis of scientific merit.

APPLICATION PROCEDURES

Applicants are to use the research project application form PHS 398 (rev. 9/91) that is available at the applicant's institutional research office and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441. Individual

fellowship applicants must use PHS 416-1 (revised 7/88). To expedite the application's routing, please check the box on the application face sheet indicating that the application is in response to this announcement and type (next to the box) "Causes & Effects of Elderly Population Concentrations, PA-92-62." The application (with five copies) must be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

If applying for an F32, the application and two copies need to be sent to the above address.

Receipt dates for Research Project Grant, Career Development Award, and FIRST Award applications are February 1, June 1, and October 1 of each year. Those for the individual fellowship (F32, F33) applications are January 10, May 10, and September 10.

INQUIRIES

Although it is not required, potential applicants are encouraged to discuss the project with program staff in advance of formal submission. This may be accomplished by calling the program office listed below.

For substantive issues and to obtain information on research resources, contact:

Behavioral and Social Research Program
National Institute on Aging
Gateway Building, Room 2C-234
Bethesda, MD 20892
Telephone: (301) 496-3136

Division of Primary Care
Center for General Health Services Extramural Research
Agency for Health Care Policy and Research
2101 E. Jefferson Street, Suite 502
Rockville, MD 20852
Telephone: (301) 227-8357

For fiscal and administrative matters, contact:

Ms. Linda Whipp
Grants and Contracts Management Office
National Institute on Aging
Gateway Building, Room 2N-212
Bethesda, MD 20892
Telephone: (301) 496-1472

Mr. Ralph Sloat
Chief of Grants Management Branch
Agency for Health Care Policy and Research
2101 E. Jefferson Street, Suite 601
Rockville, MD 20852
Telephone: (301) 227-8447

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.866. Agency Research Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241 and 41 USC 289) and be subject to PHS Grant Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

CHEMISTRY-BIOLOGY INTERFACE PREDCTORAL TRAINING

NIH GUIDE, Volume 21, Number 12, March 27, 1992

PA: PA-92-63

P.T. 44; K.W. 0720005, 1003012, 0710080, 1003006

National Institute of General Medical Sciences

PURPOSE

The National Institute of General Medical Sciences (NIGMS) announces a new predoctoral institutional training grant program directed towards training at the interface of the scientific disciplines of chemistry and biology. Chemists play a major role in the basic research supported by the NIGMS. However, their participation in NIGMS predoctoral training programs has not been at a level commensurate with the support of chemistry research by the NIGMS. The purpose of the new program is to promote interdisciplinary training and, especially, to encourage greater participation of faculty in chemistry, pharmaceutical chemistry, and medicinal chemistry departments in the predoctoral training efforts of the NIGMS.

In addition, there is a compelling economic argument in support of the creation of this new training program.

The diminishing pool of scientists trained in chemistry is considered a problem of considerable urgency by the pharmaceutical and biotechnology industries. Modern research in those industries is accomplished by interdisciplinary teams and, currently, industry must provide the interfacial training. One of the goals of this program is to provide those industries with critically needed new scientific talent trained at the interface of chemistry and biology.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic public and private institutions with established programs leading to the Ph.D. degree. It is anticipated that applications will represent a joint effort between faculty in departments of chemistry, pharmaceutical chemistry, and/or medicinal chemistry, on the one hand, and departments of biochemistry, biological chemistry, molecular biology, molecular pharmacology, immunology, and structural biology, on the other. On the chemistry side, the mechanistic/synthetic focus of the program would most likely be relevant to the fields of bio-organic, bio-inorganic, bio-analytical, and medicinal chemistry.

MECHANISM OF SUPPORT

The mechanism of support for this program announcement is the National Research Service Award (NRSA) institutional training grant (T32). The stipend level for predoctoral trainees is \$8,800 per annum. In addition, the applicant institution may request up to \$1,500 per year for each predoctoral trainee for essential direct support costs (including fees and health insurance) to the training program and \$300 per year for each trainee for travel. Tuition support for each trainee may be requested in accordance with amounts charged to other graduate students, regardless of the source of support. Indirect cost will be paid at eight percent of total allowable direct costs less tuition, fees, and health insurance. Institutional training grants are made for project periods of up to five years and are renewable. However, no single predoctoral trainee may receive more than five years of aggregate NRSA support unless a special waiver is obtained. More detail on the policies governing the institutional predoctoral training grant awards can be found in the National Research Service Awards Guidelines published in the NIH Guide for Grants and Contracts, Vol. 21, No. 11, March 20, 1992. Awards will be administered in accordance with the PHS Grants Policy Statement (10/1/90) and interim updates.

TRAINING OBJECTIVES

The NIGMS currently supports predoctoral research training through NRSA institutional training grants in six major programs: Cellular, Biochemical, and Molecular Sciences; Genetics; Molecular Biophysics; Pharmacological Sciences; Systems and Integrative Biology; and Biotechnology. The goal of the NIGMS in supporting these programs is to provide trainees with broad access to research opportunities across disciplinary and departmental lines, while not sacrificing the standards of demanding scientific depth and creativity, which are characteristic of the best Ph.D. programs of individual departments. Cooperative involvement of faculty members from several departments as research mentors and didactic lecturers is considered evidence of such breadth.

This program differs from existing NIGMS training programs in its focus on mechanistic and synthetic aspects of the chemistry-biology interface. The need for chemists who can design, synthesize, manipulate, and characterize molecules, including macromolecules, is increasing as molecular biology has uncovered a host of new targets and opportunities for chemical approaches to their study. An objective of this program is to provide chemists with training in biological science so that they can foresee the biological potential of the compounds with which they work and apply chemical principles for the design of new compounds to answer biological questions. There is also a clear need for biologists, who increasingly pursue biological problems of interest at the molecular level, to complement their primary expertise with a greater understanding of fundamental chemistry. Additional training in molecular recognition, design, synthesis, and reactivity, coupled with additional experience in chemical investigative approaches, should expand the range of tools available to biologists and enable them to explore molecular bioscience to a greater depth. This new program is intended to provide significant training in the biological sciences to chemists and significant training in chemistry to biologists and to foster a greater level of interaction between practitioners of the two fields.

Applications requesting support should reflect the following programmatic considerations:

- o Significant cross-training between chemistry and biology as the essential criterion: This must not be at the expense of training in depth in a core discipline. It is expected that training of the desired breadth and the necessary depth can be accomplished without lengthening the period of time required to obtain the doctorate degree.
- o An identity of the proposed program separate from those of the individual departments that comprise them: Programs should produce graduates that have identifiable skills, knowledge, and abilities unique to graduates of that program within the university setting. Programs will not be supported that are judged to exist mainly to procure additional departmental funding for predoctoral training.
- o Laboratory rotations for students prior to selection of a thesis mentor: Although not commonly required by chemistry departments, these should be considered as an approach for trainees to expand the breadth of their training. Especially encouraged is a cross-training experience outside the mentor's laboratory for a period of three to six months. Such an experience could be obtained through an extended rotation in a different academic laboratory or an internship in an industrial setting, before or after selection of a mentor.
- o A mechanism whereby trainees develop a common language: Biologists and chemists do not routinely speak the same language. For example, the word "molecular" has different meanings to each group. Encouraged is the implementation of a mechanism for trainees to develop a common language, such as a joint seminar program.
- o A strong institutional commitment: This is an important review criteria. One measure of the institutional commitment is cost-sharing, such as through stipend supplementation.
- o Complementarity to existing institutional training grants: Staff making awards will give attention to other

existing predoctoral programs at the applicant's institution. Overlap will be considered as well as the impact of the proposed program on the existing programs. It is expected that a program with a mechanistic/synthetic focus can be implemented that will complement existing programs without significant overlap in the trainee pool or research opportunities.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). Applicants must indicate in item 2a on the face page that the application is being submitted in response to this program announcement. Application materials are available from most university business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441.

Deadlines for receipt of applications are January 10, May 10, and September 10. It is anticipated that a limited number of awards will be made as early as September 1993. Therefore, those interested in FY 1993 awards should plan to submit applications no later than January 10, 1993. Thereafter, the latest date for applications seeking support for a given fiscal year will be May 10 of the preceding year, and start dates for awards will be July 1.

The signed original and five copies of the application must be sent to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892 **

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines and reviewed for scientific and technical merit by an existing or ad hoc study section within the assigned ICD. The applications will also receive a second level review by an appropriate national advisory council.

AWARD CRITERIA

In making funding decisions, the following will be considered: quality of the proposed program as determined by peer review, availability of funds, and program balance among training areas of the announcement.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcomed.

Direct inquiries regarding programmatic issues to:

Michael E. Rogers, Ph.D.
Deputy Director, Pharmacological Sciences Program
National Institute of General Medical Sciences
5333 Westbard Avenue, Room 919
Bethesda, MD 20892
Telephone: (301) 496-7181

Direct inquiries regarding fiscal issues to:

Toni K. Holland
Supervisory Grants Management Specialist
Office of Program Affairs
National Institute of General Medical Sciences
5333 Westbard Avenue, Room 933
Bethesda, MD 20892
Telephone: (301) 496-7897

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.859. Awards are made under the Public Health Service Act, Title IV, Part A (Public Law 99-158, as amended) and administered under PHS grants policies and Federal Regulations 42 CFR Part 66. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

RESEARCH ON HERITABLE DISORDERS OF CONNECTIVE TISSUE

NIH GUIDE, Volume 21, Number 12, March 27, 1992

PA NUMBER: PA-92-64

P.T. 34; K.W. 0705050, 1002019, 0755020, 0785035

National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Child Health and Human Development

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and National Institute of Child Health and Human Development (NICHD) invite grant applications for basic and clinical research projects on heritable disorders of connective tissue.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, non-profit and for-profit, public and private organizations, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. However, foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) Award (R29) and the career development awards (K04, K08, K11). Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Support will be offered through research projects grants (R01), FIRST awards (R29), fellowship training (F32, F33, T32), and career development awards (K04, K08, K11).

RESEARCH OBJECTIVES

Over 200 distinct disorders are recognized as being caused by mutations in genes that encode matrix proteins or in genes that ultimately affect the structure of the extracellular matrix. Collectively, these disorders are termed heritable disorders of connective tissue. There is a wide range of anatomic sites and clinical manifestations that can result from these conditions. In total, it is estimated that heritable disorders of connective tissue account for major and, in some cases, life-threatening illnesses in approximately half a million people in the United States.

Some mutations in genes may give rise to severe abnormalities, while others may produce milder symptoms. There is also recent scientific evidence that mild phenotypes may appear in more common disorders, such as osteoarthritis and osteoporosis.

On April 9-11, 1990, the NIAMS, the NICHD, and the Coalition for Heritable Disorders of Connective Tissue sponsored a Workshop on Heritable Disorders of Connective Tissue at the National Institutes of Health. The focus of the Workshop was to review the current status of research in this field and to identify important directions for future research. Major advances have been achieved in identifying molecular components of the extracellular matrix, in isolating and characterizing the genes that encode these proteins, in defining biosynthetic pathways and interactions between proteins, and in characterizing specific mutations in some disease categories.

The Workshop participants described the need for continued integration of insights gained from collaborative research perspectives, such as molecular biology, biochemistry, physical biochemistry, anatomy, and clinical genetics, the need to identify cohorts of patients and families with rare disorders, and the need to recognize structure-function relationships in interpreting genetic mutations. Some broad areas of recommended research directions include, but are not limited to:

- o Identification and characterization of mutations in many disease phenotypes;
- o Structure-function relationships of normal matrix molecules;
- o Developmental regulation of matrix formation;
- o Multi-disciplinary analysis of disease mechanisms;
- o Clinical studies: natural history and clinical trials in these disorders;
- o Identification and study of animal models using transgenic technologies;
- o Application of genetic linkage strategies to these inherited disorders;
- o Pursuit of the molecular/genetic basis of selected common diseases.

The above examples of research areas related to heritable disorders of connective tissue are not presented in a priority order and are not intended to restrict the wide range of meritorious areas in which investigators may apply. A complete report of the 1990 Workshop is available upon request from Dr. Stephen L. Gordon at the address below.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women

or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Section 2, 1-4 of the Research Plan and summarized in item 5, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including, but not limited to, clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed and the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 416-1 (rev. 4/89) for individual fellowships, for other awards use PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines indicated in the application kit.

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441. The title and number of the announcement must be typed in Section 2a on the face page of the PHS 398.

The completed original application and five legible copies of the PHS 398 or two copies of the PHS 416-1 must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by initial review groups of the Division of Research Grants, NIH, or by the review group of the relevant Institute, Center, or Division (ICD), in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that ICD. The following criteria will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review;
- o Availability of funds;
- o Program balance among research areas of the announcement.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries for the NIAMS regarding programmatic issues to:

Stephen L. Gordon, Ph.D.
Chief, Musculoskeletal Diseases Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 407
Bethesda, MD 20892
Telephone: (301) 496-7495

NIH LIBRARY



Direct inquiries for the NICHD regarding programmatic issues to:

Delbert Dayton, M.D.
Chief, Genetics & Teratology Branch
National Institute of Child Health and Human Development
Executive Plaza North, Room 643
Rockville, MD 20892
Telephone: (301) 496-5541

Direct inquiries for the NIAMS regarding fiscal matters to:

Ms. G. Carol Clearfield
National Institute of Arthritis and Musculoskeletal and Skin Diseases
5333 Westbard Avenue, Room 726B
Bethesda, MD 20892
Telephone: (301) 496-6529

Direct inquiries for the NICHD regarding fiscal matters to:

Douglas Shawver
National Institute of Child Health and Human Development
Executive Plaza North, Room 505
Rockville, MD 20892
Telephone: (301) 496-1303

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846, Arthritis, Musculoskeletal and Skin Disease Research, 93.862, Genetics Research, 93.865, Research for Mothers and Children. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78- 410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ERRATUM

BI-COMPARTMENT TRANSDERMAL CONTRACEPTIVE DELIVERY SYSTEM

NIH GUIDE, Volume 21, Number 12, March 27, 1992

RFP AVAILABLE: NICHD-CD-92-11

PT. 34; K.W. 0750020, 0740021, 0760025

National Institute of Child Health and Human Development

The notice of availability of the requests for proposals (RFP) NICHD-CD-92-11 was announced in the NIH Guide for Grants and Contracts on March 20, 1992, Vol. 21, No. 11. This erratum is to change the receipt date for proposals. Proposals will be due on June 30, 1992.

Copies of the RFP may be obtained by sending a written request to:

Paul J. Duska, Contracting Officer
Contracts Management Branch, OGC
National Institute of Child Health and Human Development
Executive Plaza North, Room 610
9000 Rockville Pike
Bethesda, MD 20892-9903
FAX: (301) 402-0915

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

5333 Westbard Avenue
Bethesda, MD 20816

NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21., No. 13
April 3, 1992

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National Institutes of Health

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This publication is also available electronically to institutions via BITNET or INTERNET. Alternative access is through the NIH Grant Line using a personal computer. Contact Dr. John James at 301/496-7554 for details, or send an E-mail message to ZNS@NIHCU.

NOTICES

NIH REGIONAL CONFERENCE IN GRANTS ADMINISTRATION

NIH GUIDE, Volume 21, Number 13, April 3, 1992

P.T. 34; K.W. 0710030, 0404000, 1014006

National Institutes of Health

A regional conference covering topics related to grants administration at the National Institutes of Health (NIH) is planned for June 6-7, 1992 at the Tremont Plaza Hotel, Baltimore, Maryland. The NIH conference will precede the Society of Research Administrators' Northeast Section meeting scheduled to be held in this same location from June 8-10, 1992.

The conference is located to attract research administrators from New England, Delaware, Maryland, Pennsylvania, Virginia, West Virginia, and Washington, DC. Those interested from other states are encouraged to attend. Faculty are welcome even though this particular seminar is intended primarily for the administrator. Staff from small and minority colleges, for-profit research organizations, hospitals, universities, and research institutes are also invited.

This two-day conference will be of interest to both new and senior grants administrators. Discussions of current issues that affect NIH funding and grants administration are included to give conference participants a comprehensive, up-to-date view of NIH-sponsored research. Topics for discussion will include science planning, cost management, effective research administration, and pre and post award issues. The format for this conference will include case studies, group discussions, and formal presentations. Time will be available for conference participants to meet informally with the NIH representatives and discuss topics of special interest.

Mr. Geoffrey Grant, Grants Policy Officer, Office of Extramural Research, representatives from the Division of Research Grants, and grants management staff of several awarding components of NIH are featured speakers.

INQUIRIES

Advance registration is required because conference space is limited to the first 200 registrants. For a conference schedule and registration information, contact:

Ms. Anita King
Telephone: (617) 638-4640

MASTER AGREEMENT FOR TUMOR TISSUE RESOURCES FOR EVALUATION OF PROMISING DIAGNOSTIC AND PROGNOSTIC APPROACHES

NIH GUIDE, Volume 21, Number 13, April 3, 1992

RFP AVAILABLE: NCI-CB-21001-32

P.T. 34; K.W. 0715035, 0780005, 0755010, 1002008

National Cancer Institute

The National Cancer Institute is seeking experienced organizations that are able to access and provide large numbers of paraffin embedded tumor tissues (or whenever available, frozen tumor specimens) with associated patient follow-up data to be used for the validation of promising new diagnostic and prognostic assays. The tumor tissue required and the assays to be performed will be defined by Master Agreement Orders (MAOs) issued during the period of performance. The MAOs will be awarded based upon competition among members of the Master Agreement (MA) pool. MA holders selected for award shall provide a minimum number of paraffin blocks (and/or frozen tissue whenever available) of breast, colorectal, and/or bladder tumor tissue of specific tumor stages with a minimum number of years of clinical follow-up. MA holders shall perform evaluations of promising new diagnostic and prognostic techniques as defined by individual MAOs. Offerors may qualify to perform one, all, or any combination, of the following methodologies: Flow cytometry studies of cell proliferation, molecular biology studies, and/or immunohistochemical assays. MAs will be awarded to all organizations whose technical proposal is considered acceptable. Multiple MAOs may be issued in each year. An MA holder is free to respond to any particular Request for Proposals (RFP) without having any affect on its MA. The proposals will be due by COB May 4, 1992.

Richard L. Hartmann
Contracting Officer's Representative
Research Contracts Branch
Cancer Etiology Contracts Section
National Cancer Institute
Executive Plaza South, Room 620
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-8611
No collect calls will be accepted.

COLLABORATIVE PROJECTS ON WOMEN'S HEALTH

NIH GUIDE, Volume 21, Number 13, April 3, 1992

RFA AVAILABLE: HL-92-07

P.T. 34, II; K.W. 0715040, 0715165, 0710030, 0413002, 1002061

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: November 13, 1992

Application Receipt Date: December 9, 1992

THE REQUEST FOR APPLICATION (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The National Heart, Lung, and Blood Institute (NHLBI) invites the concurrent submission of small groups of scientifically related research project applications related to women's health issues. The goal of this program is to foster collaborative research in currently under-investigated areas of women's health related to cardiovascular, lung, and blood diseases.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priorities. This RFA, Collaborative Projects on Women's Health, addresses several priority areas including heart disease and stroke, physical activity and fitness, and nutrition, as they relate to cardiovascular, lung, and blood diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

All domestic public and private, for-profit and non-profit institutions or organizations are eligible to apply in response to this RFA. Applications from women investigators and from minority investigators and institutions are encouraged.

MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional individual research project grant (R01). Applicants will plan and execute the research programs and are requested to furnish their own estimates of the time required to achieve the objectives of the proposed research project. Up to five years of support may be requested. At the end of the official award period, renewal applications may be submitted for peer review and competition for support through the unsolicited grant process of the NIH. It is anticipated that support for the present program will begin in July 1993. Administrative adjustments in project period and/or amount of support may be required at the time of the award. All current policies and requirements that govern the research grant programs of the NIH will apply to grants awarded in connection with this RFA.

FUNDS AVAILABLE

Although the financial plans for fiscal year 1993 include \$5,000,000 for the total costs of this program, award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that up to six collaborative groups (15-25 R01 awards) will be supported under this program. The number and specific amount to be awarded will depend on the merit and scope of the applications received and on the availability of funds.

RESEARCH OBJECTIVES

Examples of research that would be responsive to this RFA are given below. These research topics are intended to provide a perspective on the scope of research that would meet the purpose of this program. It is not required that all or any of them be included in a particular group of applications. Investigators are encouraged to consider other topics relevant to this program.

- o Assessment of myocardial perfusion and metabolism in women with the goal of distinguishing with ischemia-like chest pain, those in whom symptoms are an early manifestation of myocardial ischemia.
- o Determination of the location and concentration of vascular hormone receptors in women and/or female animal models and evaluation of receptor-mediated changes in vasomotor tone.
- o Elucidation of the mechanisms that mediate the effects of stress on lipid metabolism and atherogenesis, such as the relationship between stress, ovarian dysfunction, and premenopausal myocardial infarction.
- o Development and evaluation of interventions to promote physical activity to enhance cardiovascular and pulmonary fitness among adult women at various life stages, such as entry into the work force, parenthood, and retirement.
- o Evaluation of the effect of asthma and its treatment on pregnant women, the developing fetus, and perinatal outcome; examination of the benefits and risks of steroid therapy for asthma in postmenopausal women who have been treated with steroids for various lengths of time.
- o Investigation of mechanisms that contribute to increased airways responsiveness in women; studies of synergistic effects of airways reactivity, cigarette smoking, and environmental/occupational exposures in women.
- o Determination of whether or not aspects of nicotine dependence affect smoking cessation rates in women and whether age, life stage, physical activity, and marital, health, racial/ethnic, and socioeconomic status differentially affect cessation rates.
- o Elucidation and exploration of reproductive problems in women with sickle cell disease (SCD), e.g., specific cause of menarchial delay, effect of SCD on conception and pregnancy outcome.
- o Investigation of thromboembolic events as a function of a woman's normal development and of life stages such as pregnancy and postmenopause; determination of factors that influence response to thrombolytic agents and anticoagulants in women; and development of safe and effective anticoagulants for use during pregnancy.
- o Investigation of the role and effect of sex hormones on the hematopoietic microenvironment and the subsequent growth and differentiation of hematopoietic cells

The NHLBI will sponsor annual meetings to encourage the exchange of information among investigators who participate in this program.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF MINORITIES IN CLINICAL RESEARCH STUDIES

This RFA focuses on women. NIH and ADAMHA policy is that applicants for research grants are required to include minorities in study populations so that research findings can benefit all persons at risk of the disease, disorder, or condition under study. Special emphasis should be placed on the need for inclusion of minorities in studies of diseases, disorders, and conditions that disproportionately affect them. If minorities are excluded or are inadequately represented in clinical research, a clear, compelling rationale for exclusion for inadequate representation should be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes identification of other participating investigators and any other institutions, and a descriptive title. The NHLBI requests such letters only for the purpose of providing an indication of the number and scope of applications to be received

and, therefore, usually does not acknowledge their receipt. A letter of intent is not binding, it will not enter into the review of any application subsequently submitted, nor is it a necessary requirement for application. This letter of intent, to be received no later than November 13, 1992, is to be sent to:

Dr. Charles Turbyfill
Review Branch, Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 553
Bethesda, MD 20892

APPLICATION PROCEDURES

The research grant application form, PHS 398, (revised 9/91) is to be used in applying for these grants. This form is available in the applicant institution's office of sponsored research or business office and from the Office of Grants Inquiries, National Institutes of Health, Room 449, Westwood Building, Bethesda, MD 20892, telephone 301/496-7441.

In the preparation of the budget for the grant application, applicants should request additional travel funds for a two-day meeting each year to be held in Bethesda, Maryland. Applicants should also include a statement in the applications indicating a willingness to participate in such meetings.

Applications must be submitted by December 9, 1992

REVIEW CONSIDERATIONS

Applications judged to be responsive will be reviewed for scientific and technical merit by an initial review group that will be convened by the Division of Extramural Affairs, NHLBI, solely to review these applications.

This initial review will include a triage. The NHLBI will withdraw from further consideration applications judged to be noncompetitive and promptly notify the Principal Investigator and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated for scientific and technical merit by the usual peer review procedures.

The second level of review will be by the National Heart, Lung, and Blood Advisory Council.

INQUIRIES

Inquiries regarding this RFA and requests for the RFA may be directed to the following program administrators:

Patrice Desvigne-Nickens, M.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 3C06
Bethesda, MD 20892
Telephone: (301) 496-1081
FAX: (301) 480-6282

Carol Vreim, Ph.D.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 6A16
Bethesda, MD 20892
Telephone: (301) 496-7208
FAX: (301) 496-9886

Carol Letendre, Ph.D.
Division of Blood Diseases and Blood Resources
National Heart, Lung, and Blood Institute
Federal Building, Room 516A
Bethesda, MD 20892
Telephone: (301) 496-8966
FAX: (301) 402-1622

Elaine Stone, Ph.D., M.P.H.
Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
Federal Building, Room 604A
Bethesda, MD 20892
Telephone: (301) 496-3503
FAX: (301) 480-1357

For fiscal and administrative matters, contact:

Thomas Turley
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A12
Bethesda, MD 20892
Telephone: (301) 496-7255
FAX: (301) 402-1200

AUTHORITY AND REGULATIONS

These programs are described in the Catalog of Federal Domestic Assistance Numbers: 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grants policies and Federal regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to Health Systems Agency Review.

ONGOING PROGRAM ANNOUNCEMENTS

IMPLEMENTATION OF CARING FOR PEOPLE WITH SEVERE MENTAL DISORDERS

NIH GUIDE, Volume 21, Number 13, April 3, 1992

PA AVAILABLE: PA 92-

P.T. 34; K.W. 0715129, 0730050, 0408006, 0415001, 0417000

National Institute of Mental Health

THE PROGRAM ANNOUNCEMENT (PA) DESCRIBED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE PA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The purpose of this announcement is to encourage research, research demonstration, and research career development applications for investigations of mental health care to persons with severe mental disorders. The ultimate goal of this initiative is to improve the care and quality of life of those who suffer from persistent and disabling mental illnesses. Applications are sought in the areas of clinical services, service systems, and mental health economics.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Implementation of Caring for People with Severe Mental Disorders, is related to the priority areas of mental health objectives 6.4, 6.6, and 6.7. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by any public or private nonprofit organization and by for-profit organizations, including universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Foreign institutions may only apply for research project grants. Women and minority investigators are encouraged to apply. Special eligibility requirements for specific support mechanisms are described in the relevant announcements.

Applications for Community Support Program (CSP) research demonstration grants may be made only by State mental health authorities. It is expected that the primary researcher will be the Principal Investigator and the State staff member with project oversight responsibility will be the Project Coordinator.

MECHANISMS OF SUPPORT

Research support may be requested through applications for a research grant (R01), a small grant (R03), the First Independent Research Support and Transition (FIRST) Award (R29), and the Multi-Institutional Collaborative Research Project (R10).

Support for research projects that include funds for services may be requested through applications for research demonstration grants (R18), including CSP research demonstration grants. Other mechanisms supported by this announcement include:

National Research Service Awards

- o Predoctoral Individual M.D./Ph.D. Fellowship (F30)
- o Individual Predoctoral Fellowship (F31)
- o Individual Postdoctoral Fellowship (F32)
- o Institutional Training grant (T32)

Research Career Development Awards

- o Research Scientist Development Award (K02)
- o Research Scientist Award (K05)
- o Scientist Development Award for Clinicians (K20)
- o Scientist Development Award (K21)

RESEARCH OBJECTIVES

Clinical services research extends the work done in clinical research and provides questions for further

clinical trials. It focuses on how clinical knowledge, gained in a controlled research environment, is applied in the larger, relatively uncontrolled environment in which those with mental illness actually live. However, equally important, it is concerned with learning from community clinical practice what aspects of that care are most important in improving the outcome of mental health treatments. The primary goal of clinical services research is to improve the quality of care in everyday clinical practice.

Service systems research focuses on the organizational, financial, and social issues related to the provision of services to persons with severe mental disorders. Its goal is to identify optimum ways to organize and finance mental health and related services to meet the multiple and varying needs--psychological, social, and economic--of the individuals who suffer from severe mental disorders and of individuals who provide care to them.

Applicants may use a variety of approaches, singly or in combination, and may address any of a broad range of research issues related to mental health clinical services and service systems research. Research in the following content areas will be supported:

Clinical Services: Characteristics of the population, assessment research, treatment research, rehabilitation research, outcomes research.

Service Systems: Improving service systems, structure of care, allocation of financial resources, legal issues, human resource issues, stigma.

More detailed information regarding possible research topic areas are described in the PA.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

Applicants are to use the Public Health Service research grant application form PHS 398 (revised 9/91) (except for the F30, F31, F32). Fellowship applications must use the PHS 416-1. The number (PA-92-65) and the title of this announcement, "Caring for People with Severe Mental Disorders," must be typed in item number 2a on the face page of the PHS 398 application form. Applicants must also specify, using the appropriate code, which support mechanism they are applying under, e.g., FIRST (R29), small grant (R03), research demonstration (R18).

The signed original and five legible copies of the PHS 398 or two copies of the PHS 416-1 must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of the established PHS referral guidelines. Applications will be reviewed for scientific and technical merit by an initial review group (IRG) composed primarily of non-Federal scientific experts. Final review is by the appropriate National Advisory Council. With the exception of small grants and NRSA individual fellowship applications, when not reviewed by Council, only applications recommended by the Council may be supported. Summaries of IRG outcomes are sent to applicants as soon as possible following IRG review.

AWARD CRITERIA

For applications that are assigned to the National Institute of Mental Health (NIMH), special consideration will be given to applications that involve active collaborations between academic researchers and public sector agencies in planning, undertaking, analyzing, and publishing research pertaining to persons with severe mental illness. The Public Academic Liaison (PAL) initiative is based on the premise that important new advances in understanding and treatment of severe mental illness can result from improved linkages between the Nation's scientific resources and the public sector agencies and programs in which many persons with severe mental illness receive care. The scope of the PAL initiative encompasses public sector agencies of all types that deal with children, adolescents, adults, and elderly persons with severe mental disorders.

In addition, the NIMH will give preference in funding to projects involving underserved populations (e.g., minorities, those who live in rural areas) and projects that include females and minorities in study populations.

Factors considered in determining which applications will be funded include IRG and Council recommendations, program needs and priorities, and the availability of funds.

INQUIRIES

NIMH staff are available for consultation concerning application development in advance of or during the process of preparing an application. Potential applicants are encouraged to contact NIMH as early as possible for information regarding developing an application and to request the complete program announcement.

Inquiries related to clinical services research may be directed to:

Ann A. Hohmann, Ph.D., M.P.H.
Telephone: (301) 443-3364

Cille Kennedy, Ph.D.
Telephone: (301) 443-1330

Kathy Magruder, Ph.D., M.P.H.
Telephone: (301) 443-3364

Junius Gonzales, M.D.
Telephone: (301) 443-1330

Inquiries related to service systems research may be directed to:

Chuck Windle, Ph.D.
Telephone: (301) 443-4233

Ecford Voit, Ph.D. (mental health law)
Telephone: (301) 443-3728

Agnes Rupp, Ph.D. (mental health economics)
Telephone: (301) 443-4233

Paul Widem (mental health economics)
Telephone: (301) 443-4233

To address correspondence to any of the above named persons, use the following address:

Services Research Branch
Division of Applied and Services Research
National Institute of Mental Health
5600 Fishers Lane, Room 18C-14
Rockville, MD 20857

Inquiries related to Community Support Project research demonstrations may be directed to:

Neal B. Brown, M.P.A., or Fran L. Randolph, Dr.P.H.
Community Support Section, SDCSB
Division of Applied and Services Research
National Institute of Mental Health
5600 Fishers Lane, Room 11C-22
Rockville, MD 20857
Telephone: (301) 443-3653

For further information on grants management issues, applicants may contact:

Stephen J. Hudak
Chief, Grants Management Section
National Institute of Mental Health
5600 Fishers Lane, Room 7C-23
Rockville, MD 20857
Telephone: (301) 443-4456

AUTHORITY AND REGULATIONS

The activities of this program are described in the Catalog of Federal Domestic Assistance Nos. 93.125, 93.242, 93.282, and 93.281. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR part 74. Applications for Community Support Program demonstration grants (described in the Catalog of Federal Domestic Assistance No. 93.125), must comply with the intergovernmental review requirements of Executive Order 12372.

EXPLORATORY/DEVELOPMENTAL GRANTS IN CANCER THERAPY

NIH GUIDE, Volume 21, Number 13, April 3, 1992

PA NUMBER: PA-92-66

P.T. 34; K.W. 0715035, 0755015, 0740015, 0740020, 0745062, 0785210

National Cancer Institute

PURPOSE

The National Cancer Institute (NCI) encourages the submission of exploratory/developmental grant applications for new pilot, phase I or phase II, therapeutic clinical trials that take advantage of recent laboratory developments. New and experienced investigators may submit an application to test or develop new treatment

strategies or to conduct pilot studies relevant to the following areas of clinical research: (1) treatment of breast, prostate, lung, ovarian, and cervical cancer; (2) therapies to overcome resistance to cytotoxic and biological anti-cancer agents.

The exploratory/developmental grant (R21) mechanism is utilized to encourage the development of new research activities in categorical areas of special importance. This Program Announcement (PA) supersedes the PA, "Small Grants for Lung, Breast, and Ovarian Cancer Clinical Trials (PA-92-06)," that was published in the NIH Guide for Grants and Contracts, Vol. 20, No. 37, October 4, 1992. The exploratory/developmental grant program provides limited funds (maximum of \$48,000 direct costs per year) for short-term (up to two years) research projects.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Exploratory/Developmental Grants in Cancer Therapy, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications may be from a single institution or may include arrangements with one or more institutions (e.g., consortia, clinical cooperative group) if appropriate. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Support of the program will be through the National Institutes of Health (NIH) exploratory/developmental grant (R21) mechanism. Applicants will be responsible for the planning, direction, and execution of the proposed project. All PHS and NIH grants policies will apply to applications received and awards made in response to this announcement. The direct costs of an award may not exceed \$48,000 per year. The total project period for applications submitted in response to the present PA may not exceed two years. These grants are non-renewable and continuation of projects developed under this program will be through the traditional unsolicited grant program.

RESEARCH OBJECTIVES

A. Background

At present there is no mechanism targeted to stimulate the communication of promising and potentially relevant new developments from the laboratory to the clinical setting. There is a need for a rapid mechanism to fund short-term studies and obtain preliminary clinical data. The purpose of this PA is to encourage applications from individuals who are interested in conducting clinical trials in patients with cancer using new agents or therapeutic approaches. These clinical studies would not be developed fully enough for a standard R01 and would therefore be considered high risk. It is expected that these R21 grants will serve as a basis for planning future clinical research grant applications (R01) or NCI cooperative clinical trial group studies.

Two areas of special interest to NCI have been identified for the solicitation of R21 grant applications. The first area involves solid tumors, which have been identified in the Conference Report of the United States Congress accompanying the Fiscal Year 1992 appropriation bill as priority areas of research. These include breast, prostate, ovarian, and cervical cancer, which together account for 18 percent of the cancer mortality in the United States. In addition to these tumor sites, lung cancer has also been included in this PA since it is the most prevalent cancer site and accounts for 28 percent of cancer mortality.

The second area of research targeted in this PA is that involving clinical studies designed to identify and overcome resistance to cancer therapy. A formidable challenge to cancer therapeutics continues to be the emergence and growth of treatment-resistant tumor cells after the initial response to therapy. Recent research efforts concerning this phenomenon have resulted in the identification of a number of genotypic and phenotypic alterations that appear to correlate with the development of resistance to cytotoxic and biological anti-cancer agents. Preclinical efforts have also resulted in the development of new clinical strategies to overcome this resistance. Research directed at correlating the results of laboratory assays of drug resistance with results of clinical trials is an essential step in the development of effective regimens of cancer therapeutics.

B. Research Goals and Scope

The aim of this initiative is to stimulate pilot, phase I, or phase II therapeutic clinical trials to move new treatment strategies more rapidly from the laboratory into the clinic. Clinical studies must involve human subjects and be designed to ultimately improve cancer treatment. The clinical studies must be based on a strong rationale and preclinical data should support the underlying hypothesis. The research plan should be focused on the clinical trial proposed. Laboratory studies to address the mechanism of action of agents utilized in the clinical studies or pharmacology studies may be included, but are not necessary.

Applications must be focused on one of two research areas for this Program Announcement:

1. Pilot, phase I, or phase II clinical trials for the treatment of breast, lung, prostate, ovarian, or cervical cancer. New therapeutic studies utilizing drugs, biologics, radiation, or surgery, whether used as a single agent/modality or in combination are appropriate.

2. Pilot, phase I, or phase II clinical trials directed at investigating specific strategies for overcoming or reversing clinical resistance to cytotoxic and biological anti-cancer agents. Inclusion of assays to measure phenotypic or genotypic alterations correlated to resistance are appropriate. The clinical trials can be focused on any type(s) of carcinoma.

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in #1-4 of the Research Plan AND summarized in #5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventative strategies), diagnosis, or treatment or diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, Westwood Building, National Institutes of Health, Room 449, Bethesda, MD 20892, telephone 301/496-7441. The title and number of the announcement must be typed in line 2a on the face page of the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator must be included with the application.

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by an appropriate national advisory council or board.

Review criteria that will be used to assess the scientific merit of an application are:

- o Originality of the approach
- o Soundness of the experimental design
- o Track record and commitment of the investigator(s)
- o Resources and environment
- o Appropriateness of the budget

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that ICD. The following will be considered in making funding decisions:

- o Quality of the proposed research as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

To obtain a copy of the supplemental instructions, contact the program director, Ms. Diane Bronzert, at the address below. Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Ms. Diane Bronzert, Program Director
Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

Written and telephone inquiries of a budgetary, administrative, and/or policy nature are to be directed to:

Ms. Carolyn Mason
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
6120 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7800, extension 59
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.393, 93.394, 93.395, 93.396, and 93.399. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ERRATUM

ACADEMIC RESEARCH ENHANCEMENT AWARD

NIH GUIDE, Volume 21, Number 13, April 3, 1992

PA: PA-92-28

P.T. 34; K.W. 0710030, 0404000, 1014006

National Institutes of Health

Application Receipt Date: June 19, 1992

The Academic Research Enhancement Award (AREA) program and its Program Guidelines were announced in the NIH Guide for Grants and Contracts Vol. 21, No. 1, January 10, 1992. The purpose of this notice is to clarify the page limitation for applications as stated in the AREA Program Guidelines.

The entire application cannot exceed 20 pages. This page limitation DOES NOT INCLUDE BIOGRAPHICAL SKETCHES, the CHECKLIST PAGE, the PERSONAL DATA SHEET, LETTERS OF COMMITMENT FROM CONSULTANTS, OR the INTRODUCTION (in the case of REVISED APPLICATIONS). Further information in the Program Guidelines regarding the number of pages per item ARE NOT TO BE VIEWED AS ABSOLUTE MAXIMUMS. For example, it is perfectly acceptable for the BACKGROUND and SIGNIFICANCE portion of the application to contain more than two pages and for the RESEARCH DESIGN and METHODS section to consist of more than four pages. However, each applicant organization must ensure that all appropriate sections of the application have been addressed and that the application conforms to the OVERALL LIMITATION OF 20 PAGES.

INQUIRIES

Questions regarding eligibility, policies, procedures, and other administrative aspects of the NIH AREA Program that remain AFTER CONSULTATION WITH THE INSTITUTIONAL OFFICE may be addressed to:

Research Training and Special Programs Office
National Institutes of Health
Building 31, Room 5B44
Bethesda, MD 20892
Telephone: (301) 496-1968



3 1496 00508 8953

**THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:

5333 Westbard Avenue
Bethesda, MD 20816

NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21., No. 14
April 10, 1992

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This publication is also available electronically to institutions via BITNET or INTERNET. Alternative access is through the NIH Grant Line using a personal computer. Contact Dr. John James at 301/496-7554 for details, or send an E-mail message to ZNS@NIHCU.

NOTICESNCI OUTSTANDING INVESTIGATOR AWARD

NIH GUIDE, Volume 21, Number 14, April 10, 1992

P.T. 34; K.W. 1014006

National Cancer Institute

In order to be able to meet NIH cost containment objectives (NIH Guide, Vol. 20, No. 28, July 19, 1991), the National Cancer Institute is currently reviewing options for revision of the guidelines and purposes of its Outstanding Investigator Grant (OIG) (R35) program. To reduce additional commitments during this period of evaluation, new type 1 applications will not be accepted for the previously announced June 1, 1992, receipt deadline. In the interim, NCI will rely on careful consideration of highly meritorious competing R01

applications for funding as MERIT awards to provide longer term support for individual projects of exceptional potential.

To avoid disruption of ongoing OIG awards, competing continuation applications (type 2) for OIG grants that currently are in the fifth (05) year or later will continue to be accepted and may be submitted by June 1, 1992.

Future receipt dates and a notice of availability of revised OIG guidelines will be published subsequently in the NIH Guide.

For additional information or for questions concerning this notice, contact:

Mrs. Barbara S. Bynum
Director, Division of Extramural Activities
National Cancer Institute
Building 31, Room 10A03
Bethesda, MD 20892
Telephone: (301) 496-5147
FAX: (301) 402-0062

NIH AIDS RESEARCH LOAN REPAYMENT PROGRAM

NIH GUIDE, Volume 21, Number 14, April 10, 1992

P.T. 23; K.W. 0720005, 1014006

National Institutes of Health

Application Receipt Dates: April 27, 1992, August 1, 1992

PURPOSE

This notice is a republication, with minor modifications, of a December 13, 1991 (Vol. 20, No. 46), issuance on this subject. It is being reissued to emphasize its availability.

On November 4, 1988, the United States Congress enacted Public Law 100-607, directing the National Institutes of Health (NIH) to establish an educational loan repayment program to attract investigators into Acquired Immunodeficiency Syndrome (AIDS) research. The NIH AIDS Research Loan Repayment Program (LRP), in order to increase the number of investigators conducting AIDS research at the NIH, invites interested health professionals to apply for LRP participation.

The LRP may pay a maximum of \$20,000 a year directly to a participant's lenders for qualifying educational debt during an initial, minimum two-year service period. The actual loan repayment is based, in part, on the availability of funding and the proportion of the participant's qualifying debt relative to the NIH basic pay or stipend received. Since such payments to lenders are considered income for the participant and increases his/her Federal tax liability, the LRP also makes payments, equal to 39 percent of the total loan repayments, directly towards the participant's Internal Revenue Service (IRS) account. The LRP may make additional tax reimbursements to those participants who show an increase in State and/or local tax liability. Benefits are paid in addition to a participant's annual NIH basic pay or stipend.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, NIH AIDS Research Loan Repayment Program, is related to the priority area of HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017 001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402 9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

An applicant becomes eligible for LRP participation when his/her qualified AIDS research assignment is approved by the AIDS Research Loan Repayment Advisory Committee (LRAC) and his/her contract is executed. Specific LRP applicant and participant eligibility criteria also include the following:

- (1) Applicants must be citizens or permanent residents of the United States;
- (2) Applicants must have a Ph.D., M.D., D.O., D.D.S., D.M.D., D.V.M., or equivalent degree;
- (3) Applicants must have qualified educational debt in excess of 20 percent of their annual NIH basic pay or stipend on the date of program eligibility resulting from governmental or commercial loans obtained to support their undergraduate and/or graduate education;
- (4) Individuals who are not NIH employees, such as Visiting Fellows, Intramural Research Training Award (IRTA) recipients, National Research Service Award (NRSA) recipients, Guest Researchers and Special Volunteers, NIH, National Research Council (NRC) Biotechnology Research Associates Program participants, and Intergovernmental Personnel Act (IPA) participants, may NOT participate in the LRP;
- (5) Individuals employed by the NIH during the period of November 4, 1987, through November 3, 1988, are INELIGIBLE;

(6) Applicants may be appointed under a temporary or permanent employment mechanism, if the employment has the potential to last a minimum of two years;

(7) Individuals with existing service obligations to Federal, State, or other entities will NOT be considered for the LRP unless deferrals are granted for the length of their LRP service obligation; and

(8) Applicants will NOT be excluded from consideration under the LRP on the basis of race, color, creed, religion, sex, handicap, age, national origin, or political affiliation.

In addition, in order to qualify for repayment, LRP applicants' debts are subject to the following limitations and restrictions:

The LRP will repay lenders for the principal, interest, and related expenses (such as the required insurance premiums on the unpaid balances of some loans) of qualified Government (Federal, State, and local) and commercial educational loans obtained by participants for the following: (1) undergraduate, graduate, and health professional school tuition expenses; (2) other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and (3) reasonable living expenses, including the cost of room and board, transportation and commuting costs, and other reasonable living expenses as determined by the LRP.

The following loans are NOT repayable under the LRP: (1) loans not obtained from a Government entity or commercial lending institution, such as loans from friends, relatives, or other private individuals; (2) loans for which contemporaneous documentation is not available; (3) loans or portions of loans obtained for educational or living expenses that exceed the "reasonable" level as determined by the standard school budget for the year in which the loan was made, and are determined by the LRP to be unreasonable based on additional documentation provided by the applicant; and (4) loans, financial debts, or service obligations incurred under the Physicians Shortage Area Scholarship Program, NRSA Program, Public Health and National Health Service Corps Scholarship Training Program, National Health Service Corps Scholarship Program, Armed Forces (Army, Navy, or Air Force) Health Professions Scholarship Program, and Indian Health Service Scholarship Program.

Loans in default, or loans not current in payment schedule, will not be considered as qualifying for repayment. Repayments will only be made for loans with current payment status. During lapses in loan repayments, due either to program administrative complications or a break in service, participants are wholly responsible for making payments or any other arrangements that maintain loans in a current payment status. Penalties assessed to participants as a result of LRP administrative failures to maintain current payment status may be considered for reimbursement.

Payments will NOT be made under the LRP for loans that participants have paid prior to the program eligibility date.

RESEARCH OBJECTIVES

The LRP is designed to attract additional investigators into AIDS research. The LRP intends to fund individuals conducting AIDS research as described in the following paragraphs that contain the "Activities Constituting AIDS Research" criteria as adopted by the LRAC on September 20, 1991:

"The following parameters define whether or not a proposed research assignment meets the criteria for coverage under the NIH AIDS Research Loan Repayment Program - that is, whether or not the incumbent will be "primarily" engaged in AIDS research. "Primarily" engaged in AIDS research is defined as AIDS research activities that constitute at least 80 percent of a researcher's time. Clinical Associates whose intent is to primarily engage in AIDS research must engage in qualified AIDS research for at least three months in the first year of their program, with a total of fifteen months of qualified AIDS research during their two year contract.

"AIDS research includes studies of the human immunodeficiency virus (HIV), the pathophysiology of HIV infection, the development of models of HIV infection and its sequelae, cofactors predisposing to HIV infection and AIDS, or its sequelae, and the development of vaccines and therapeutics. More specifically, the following research activities are included: (1) studies of HIV and related retroviruses; (2) studies of the mechanism(s) by which HIV and related retroviruses establish infection and infect host cells; (3) studies of the mechanism(s) by which HIV and related retroviruses cause disease, including studies of the immune deficiency induced by HIV and related retroviruses; (4) studies of the pathophysiology of host response to HIV infection; (5) studies of in vivo or in vitro models of human HIV infection and its sequelae; (6) epidemiologic studies of HIV and related retrovirus infection; (7) clinical trials involving prophylaxis or therapy for HIV infection or its sequelae; (8) preclinical studies aimed at the development of therapy for or prevention of HIV infection and the immunodeficiency caused by HIV infection and its sequelae; (9) cofactors predisposing to acquiring HIV infection; (10) basic studies and clinical trials involving vaccines, or other immunological or chemotherapeutic interventions for the prevention of HIV infection and its sequelae; and (11) basic studies into the transmission of HIV involving high risk behaviors and research concerning the interruption of transmission by behavioral change and pharmacologic intervention.

"AIDS researchers include scientists who are intellectually engaged in the process of providing scientific direction and guidance in programs of original AIDS research, specifically epidemiologists, statisticians, and others who are involved in the design and conduct of research studies. The duties of such scientists may include the generation and design of studies and the collation and analysis of data; and/or the preparation and publication, as author or co-author, of studies in peer-reviewed journals. AIDS researchers also include physicians who are providing care for HIV-infected individuals who are subjects of HIV-related research."

APPLICATION PROCEDURES

Individuals wishing to apply to the LRP must first obtain a firm employment commitment from an Institute, Center, or Division (ICD) Personnel Department. An initiating official, which may be a laboratory or branch

chief, must recommend an individual for application to the LRP, and the ICD Scientific Program Director and ICD Director must concur. LRP participation is contingent, in part, upon employment with the NIH, and candidates may not be recommended for loan repayment by an ICD until a firm employment commitment has been made by the ICD Personnel Department.

Applicants must submit a signed contract, along with their completed LRP application package, to be considered for participation in the program.

At the conclusion of the initial contract, participants may reapply and be considered for subsequent, one-year continuation contracts. Continuation contracts are based upon the same review criteria as the initial contract, in addition to a submission that describes AIDS research accomplishments made during the initial contract. These continuation contracts are approved on a year-to-year basis and contingent upon the appropriation and availability of funds.

REVIEW PROCEDURES

Completed applications to the LRP are reviewed by the LRAC. The LRAC, which is composed of intramural and extramural scientific staff, reviews, ranks, and approves or disapproves applicants. LRAC approval, in part, is based on the appropriateness of the applicant's research assignment to AIDS research and the scientific merit of the research. In addition, the credentials provided in the application are reviewed and ranked to assess the applicant's potential to conduct qualified AIDS research.

AWARD CRITERIA

The award of funds for approved applications is contingent, in part, upon the availability of funds appropriated by the Congress of the United States for the NIH. Funds will not be awarded to disapproved applicants. In return for the repayment of educational loans, participants must agree (1) to be "primarily" engaged in qualified AIDS research, which is described above in the "Activities Constituting AIDS Research" criteria, as NIH employees for a minimum period of two years; (2) make payments to lenders on their own behalf for periods of Leave Without Pay (LWOP); (3) pay monetary damages as required in cases where the initial contract is breached; and (4) all other provisions agreed upon in the contracts. Substantial monetary penalties will be imposed for breach of contract.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Information regarding the LRP may be obtained by calling or writing to:

Mr. Marc S. Horowitz, J.D.
Director, NIH AIDS Research Loan Repayment Program
Office of AIDS Research
National Institutes of Health
Building 31, Room 5C12
Bethesda, MD 20892
Telephone: (301) 402-0192

AUTHORITY AND REGULATIONS

The LRP is described in the Catalog of Federal Domestic Assistance No. 93.936. Awards are made under authorization of section 487A of the PHS Act (42 U.S.C. 288-1), as amended by section 634 of the Health Omnibus Programs Extension of 1988 (Pub. L. 100-607). This program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs, and was granted clearance from the Office of Management and Budget (0925-0361), under the requirements of the Paperwork Reduction Act of 1980, on June 15, 1990.

HEALTH AND SAFETY GUIDELINES FOR GRANTEES AND CONTRACTORS

NIH GUIDE, Volume 21, Number 14, April 10, 1992

P.T. 34; K.W. 1014002, 0725010, 0725020

National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration

This notice is a republication, with modifications, of previous issuances on this subject. It is being reissued to emphasize its continuing importance.

Organizations receiving grant or contract awards are responsible for protecting their personnel from hazardous conditions, while the Government, generally is not legally liable for accidents, illnesses, or liability claims arising out of research performed under its awards. The National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) are nonetheless concerned that a variety of hazards may threaten the safety and health of both laboratory and clinical research personnel. Accordingly, the publications listed below are designed to help identify potential hazards and inform awardee organizations and investigators of certain guidelines and standards that should be considered in addressing particular health and/or safety concerns. It should be noted that significant concerns about potentially hazardous conditions could result in grant or contract funding delays until those concerns have been resolved to the satisfaction of the awarding component.

1. Types of potential hazards to research personnel include the following:

- a. Biohazards (e.g., Human Immunodeficiency Virus, HIV; other infectious agents; oncogenic viruses).
- b. Chemical hazards (e.g., carcinogens; chemotherapeutic agents; other toxic chemicals; flammable or explosive materials).
- c. Radioactive materials.

2. The following guidelines and standards contain information designed to assist grantees and contractors in assessing potential hazards and providing a safe work environment for research personnel. Therefore, depending upon the particular safety hazard at issue, one or more of these documents should be consulted by grantees or contractors. (Items a through h).

a. Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services; Centers for Disease Control and the National Institutes of Health, HHS Publication No. (CDC) 88-8395.

b. Recommendations for Prevention of HIV Transmission in Health-Care Settings. Morbidity and Mortality Report, August 21, 1987, Vol. 35, No. 28.

c. Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings. Morbidity and Mortality Weekly Report, June 24, 1988, Vol. 37, No. 24.

d. NIH Guidelines for the Laboratory Use of Chemical Carcinogens, NIH Publication No. 81-2385.

Single copies of the above documents (Items a through d) may be obtained from:

Division of Safety (9/91)
Office of Research Services
National Institutes of Health
Building 31, Room 1C02
Bethesda, MD 20892

Additional copies to be purchased at a cost of \$3.75/copy through:

Government Printing Office
Superintendent of Documents
Washington, DC 20402
Stock# 17-40-508-3

e. Guidelines for Research Involving Recombinant DNA Molecules (49 FR 46266 or latest revision) and Administrative Practices Supplement. These guidelines may be obtained from: Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, MD 20892.

f. Procedures for the Domestic Handling and Transport of Diagnostic Specimens and Etiologic Agents, National Committee for Clinical Laboratory Standards, July 17, 1985, Vol. 5, No. 1. These procedures may be obtained from: National Committee for Clinical Laboratory Standards, 771 East Lancaster Avenue, Villanova, PA 19085.

g. Standards issued pursuant to the National Occupational Safety and Health Act of 1970 (29 CFR Part 1910).

Copies may be obtained from:

Occupational Safety and Health Administration
National Training Institute Building
1555 Times Drive
Des Plaines, IL 60018

h. Standards issued pursuant to the Atomic Energy Act of 1954 (42 USC 2021). Contact Regional Office of Nuclear Regulatory Commission.

The following materials also are recommended and may be purchased from:

National Academy Press
2102 Constitution Avenue, N.W.
Washington, DC 20418

A. Prudent Practices for Handling Hazardous Chemicals in the Laboratory. Price \$19.95

B. Prudent Practices for the Disposal of Chemicals from the Laboratory. Price \$19.95

C. Biosafety in the Laboratory: Prudent Practices for Handling and Disposal of Infectious Materials. Price \$29.95

3. Identification of Hazards

a. Preaward

Grant and cooperative agreement (hereafter will be referred to grant(s)) applications and contract proposals posing special hazards typically are identified in the review process, but such concerns can formally be expressed by agency staff or consultants at any time prior to award. If these hazards are not addressed, the awarding component must ascertain how the special hazards will be handled or the grant/contract funding could

be delayed until the matter has been resolved to the satisfaction of the awarding component.

b. Postaward

Grant Mechanism: The grantee must inform the awarding component of the nature and extent of the hazard, as well as the corrective action(s) taken or planned to prevent future occurrence. If the hazard is not adequately controlled, it may create a danger and adversely impact the activities being funded so that it impinges upon progress, efficient and effective management of resources, and research findings. The adverse impact may cause the grantee to materially fail to comply with the terms of the grant. This may lead the awarding office to take postaward action, including suspension or termination of the grant, in order to resolve the situation. (See 45 CFR 74.113 et seq. and the appeal rights set forth in 42 CFR Part 50, subpart D and 45 CFR Part 16) Postaward action also may be necessary if the application had addressed the issue of special hazards but the grantee does not adequately control the special hazards as was indicated in the application.

Contract Mechanism: Special hazards that are identified after an award is made may lead to suspension or termination of work under the contract pending corrective action by the contractor. (See 48 CFR 12.5 concerning contract "stop work" orders and the Clause at 48 CFR Part PHS 352.223-70, Safety and Health (APR 1984).

NOTICES OF AVAILABILITY (RFPs AND RFAs)

A PROSPECTIVE COHORT STUDY OF CANCER AMONG MEN AND WOMEN IN AGRICULTURE (FIELD STATIONS)

NIH GUIDE, Volume 21, Number 14, April 10, 1992

RFP AVAILABLE: NCI-CP-21096-21

P.T. 34; K.W. 0715035, 0785055, 0755030

National Cancer Institute

PLEASE NOTE: This announcement has been published in the Commerce Business Daily. Because of the late date of this announcement in the Guide, it is published for information purposes only.

The National Cancer Institute (NCI) is seeking contractors to perform the above named project. The contracts will create a field station(s) for epidemiologic studies in states that produce grain and livestock and/or in states with a significant proportion of minority farmers that produce other nonperishable commodities. It is anticipated that at least two field stations will be necessary to create a large cohort (approximately 156,000 persons) that can be followed prospectively for 10 years or more to obtain detailed information on agricultural exposures, diet, cooking practices, and other factors of etiologic interest for the study of cancer and other diseases. The field station(s) shall be located in a state(s) with population-based cancer registries and pesticide applicator registries with at least 20,000 registrants. It is desirable, but not mandatory, for the state to also have a birth defects registry. The study is designed to investigate biomarkers of exposure and disease. The entire cohort will include farm owner/operators (70,000), their spouses (56,000), or commercial and noncommercial applicators (30,000). The cohort will be assembled by enrolling applicators as they come to obtain or renew a pesticide application license at the Agricultural Extension Service Offices. The spouses of farm applicators will be invited to enroll in the cohort when their spouse is enrolled. It is anticipated that it will take three to four years to assemble the entire cohort since licenses are renewed on a three-four year cycle in many states.

The NCI expects to award three cost-reimbursement, completion type contracts for a 60-month period. The Request for Proposals (RFP) was available on March 23, 1992 and proposals are due by April 27, 1992. Awards are anticipated by September 30, 1992. All responsible sources meeting the criteria are encouraged to submit an offer and will be considered by the NCI. No collect calls will be accepted. Copies of the RFP may be obtained by submitting a written request to:

Barbara A. Shadrick, Contract Specialist
Research Contracts Branch, OD
Cancer Etiology Contracts Section
National Cancer Institute
Executive Plaza South, Suite 620
Bethesda, MD 20892
Telephone: (301) 496-8611

CONTINUATION OF FOLLOW-UP OF DES-EXPOSED COHORTS

NIH GUIDE, Volume 21, Number 14, April 10, 1992

RFP AVAILABLE: NCI-CP-33011-21

P.T. 34; K.W. 0715035, 0785055, 0775020

National Cancer Institute

The National Cancer Institute (NCI) is seeking investigators in a collaborative effort to continue follow-up of surviving members of a cohort exposed to DES given in pregnancy and designated unexposed comparison subjects. Each cohort shall consist of at least 300 people (mothers, daughters, and sons). The combined cohort (inclusive of all collaborative investigators) shall include at least 3,500 people exposed in utero (daughters and sons) and at least 2,600 women exposed during pregnancy (mothers). Unexposed subjects that can be compared to

daughters or sons shall be included, but unexposed subjects comparable to mothers shall not. It is anticipated that outcomes shall be ascertained by questionnaire and record review, not by clinical examination. Clinical examinations shall be conducted only for cohort members who have not been examined before, for example, new entrants. It should be noted that an offeror may propose to provide the names, addresses, and other locating data to NCI and not conduct follow-up of the cohort. The contractor will participate in all other contract activities, but the NCI will provide for the follow-up of cohort members. In addition, an offeror may propose to participate in all other cohort activities but not to conduct tracing of the cohort. The NCI will trace the lost cohort members. These variations must be clearly noted in the proposals and the subsequent budgets must be adjusted accordingly. This project is a research effort. The NCI expects to make one cost-reimbursement, completion type contract. All responsible sources meeting the criteria are encouraged to submit an offer that will be considered by the NCI. The Request for Proposals (RFP) was available on March 30, 1992. The proposals are due by COB May 14, 1992 with the award anticipated by September 30, 1992. No collect calls will be accepted. Copies of the RFP may be obtained by submitting a written request to:

Barbara A. Shadrick, Contract Specialist
Research Contracts Branch, OD
Cancer Etiology Contracts Section
National Cancer Institute
Executive Plaza South, Suite 620
Bethesda, MD 20892
Telephone: (301) 496-8611

SCIENCE TEACHING ENHANCEMENT AWARD PROGRAM

NIH GUIDE, Volume 21, Number 14, April 10, 1992

RFA AVAILABLE: OD-92-03

P.T. 25; K.W. 0720000, 0720005

National Institutes of Health

Letter of Intent Receipt Date: May 10, 1992
Application Receipt Date: June 10, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The National Institutes of Health, through the National Center for Research Resources (NCRR), invites grant applications for a pilot Science Teaching Enhancement Award Program (STEAP). The Science Teaching Enhancement Award will prepare highly qualified middle/junior and high school science teachers to become lead teachers to work as liaisons with academic medical centers, universities, and other health professional schools to improve teaching in the biomedical sciences of grades 6-12. This announcement describes a two-year program to test the feasibility and the effectiveness of the STEAP for improving the quality of pre-college biomedical science education.

ELIGIBILITY REQUIREMENTS

Because of the pilot nature of this activity, eligibility will be limited. First, to ensure that institutions have a minimum amount of NIH research activity upon which to draw for this initiative, eligible institutions must be recipients of a 1991 Biomedical Research Support Grant (BRSG) award or a 1992 Minority High School Student Research Apprentice Program (MHSSRAP) award. Second, to ensure that the quality of science teaching at the 6-12 grade levels and the science literacy of the general public will be enhanced nationwide, eligibility is limited to those states that historically have been relatively less competitive in obtaining NIH grant support. For purposes of this RFA, eligibility is thus limited to FY 1991 BRSG or FY 1992 MHSSRAP institutions in Alaska, Arkansas, Delaware, Hawaii, Idaho, Kentucky, Maine, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Puerto Rico, South Carolina, South Dakota, West Virginia, Wyoming. In addition, if an institution has both a BRSG and a MHSSRAP program, only one STEAP application may be submitted. Focusing on states that have a small research base will make it more feasible to assess and evaluate the success of the pilot program in producing experienced, knowledgeable lead teachers who can act as liaisons between research institutions and the teachers, science educators, and other administrators in the local community school system. In addition, by broadening the geographic areas served, the impact of NIH current science education activities will be expanded by stimulating the scientific interests of a new cadre of pre-college students and teachers, and thus opening the scientific pipeline to a wider range of future biomedical scientists.

MECHANISM OF SUPPORT

This RFA will use the grant-in-aid for education projects (R25). Applicants will be responsible for the planning, direction, and conduct of the proposed program. The total project period for applications submitted in response to this RFA may not exceed two years. The anticipated award date will be September 30, 1992.

This RFA is a one-time solicitation. At the conclusion of this pilot activity, the NIH will assess the feasibility of continuing the program. Thus, no unsolicited competing continuation applications will be accepted at the conclusion of this pilot initiative. Although NIH hopes to continue the program beyond the pilot phase, there is neither a guarantee of continuation, nor, if the program is continued, is there a guarantee of its future design.

FUNDS AVAILABLE

Up to \$500,000 will be available from the Office of the Director, NIH, in Fiscal Year 1992 to support this initiative. NIH staff anticipate making 6-10 2-year awards using multi-year funding. This level of support is dependent upon the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the Office of the Director, NIH, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The objective of this RFA is to increase the number of middle/junior and high school science teachers who are motivated to: (1) become involved in active research projects to enhance their instructional skills and their scientific knowledge so that current concepts in health science can be integrated into the students' curricula, (2) develop and test curricula for classroom settings, and (3) provide linkages among professional scientists, teachers, and school programs to foster mentoring and encourage the pursuit of science by students.

The two-year program should include year round activities for a core of three lead teachers to familiarize the educators with basic vocabulary and concepts in selected areas of biomedical science of contemporary interest, library use and the use of computers in teaching; provide a hands-on laboratory experience that is an appropriate research project; development of teaching modules and instructional materials geared to the grades taught; and other enrichment experiences including workshops, seminars, and other classroom activities.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 10, a letter of intent that includes a descriptive title of the proposed program, the name, address, and telephone number of the Principal Investigator, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information contained is helpful in planning for the review of applications. It allows NIH staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Dr. Marjorie A. Tingle
Director, Biomedical Research Support Program
National Center for Research Resources
Westwood Building, Room 10A11
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-6743

APPLICATION PROCEDURES

Applicants must request the RFA which contains additional information for applying under this RFA. Applications are to be submitted using form PHS 398 (rev. 9/91). These forms are available in most institutional business and sponsored programs offices and may be requested from the Office of Grants Inquiries, Division of Research Grants, NIH, 5333 Westbard Avenue, Bethesda, MD 20892, telephone (301) 496-7441.

Applications must be submitted by June 10, 1992. Applications submitted after this date will be returned to the applicant.

REVIEW CONSIDERATIONS

Review of the STEAP grant applications for scientific and technical merit will be performed by an ad hoc review committee. The top two thirds of applications will undergo a second level review for policy and programmatic issues by the National Advisory Research Resources Council.

The factors to be considered with the evaluation of each application will include: (1) the educational and scientific merit of the proposed program; (2) the manner in which it will improve biomedical science education at the precollege level; (3) the criteria for selecting teachers and mentors; (4) the mixture of laboratory and didactic exercises; (5) the quality of the proposed research experiences; (6) the quality of the proposed enrichment experiences and support activities; (7) the potential for substantially enhancing precollege education by having teachers prepared to incorporate what they have learned into their own teaching and to conduct continuing education for their colleagues; (8) the proposal to develop improved materials and methods for classroom use; (9) evidence of support from school systems of potential teacher candidates; (10) willingness to participate in the evaluation component of the program; (11) the quality of the overall plan for administration of the program; and (12) the potential for participant teachers to take leadership roles in the in-service training of their peers in their home schools and communities.

AWARD CRITERIA

In making funding decisions, the Office of the Director, NIH, and the NCRR will give consideration to ensure program balance among various types of programs and/or geographic distribution in the United States and its territories.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Dr. Marjorie A. Tingle
Director, Biomedical Research Support Program
National Center for Research Resources
Westwood Building, Room 10A11
Bethesda, MD 20892
Telephone: (301) 496-6743

Direct inquiries regarding fiscal matters to:

Ms. Mary V. Niemiec
Supervisory Grants Management Specialist
Office of Grants and Contracts Management
National Center for Research Resources
Westwood Building, Room 849
Bethesda, MD 20892
Telephone: (301) 496-9840

AUTHORITY AND REGULATIONS

Awards will be made under authorization of the Public Health Service Act, Title III, Part A (Public Law 78-410, as amended, 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

INTERNATIONAL GENOME RESEARCH COLLABORATIVE PROGRAM FOR CENTRAL AND EASTERN EUROPE

NIH GUIDE, Volume 21, Number 14, April 10, 1992

PA NUMBER: PA-92-67

P.T. 34; K.W. 1215018, 0755045, 1004008

National Center for Human Genome Research
Fogarty International Center

PURPOSE

The main purpose of the International Genome Research Collaborative Program (IGRCP) is to facilitate collaboration between U.S. and Central and Eastern European scientists that will enhance the NIH-supported Human Genome Program, while at the same time benefiting the genome programs of the collaborating foreign scientists and their home institutions. For the purposes of this program, Central and Eastern Europe is defined as Bulgaria, the Czech and Slovak Federal Republic, Hungary, Estonia, Latvia, Lithuania, Poland, Romania, all republics of the (former) U.S.S.R., and Yugoslavia. As a result of new developments in Central and Eastern Europe, some of these scientists are already working in U.S. laboratories to take advantage of new scientific and technological advances. A few of them have either initiated or participated in genomic research or have the types of expertise that could accelerate the progress of the Human Genome Program. The National Center for Human Genome Research (NCHGR) would like to capitalize on these efforts and the talents of these scientists by assisting in the establishment of long-term scientific collaborations with their U.S. hosts. To accomplish these goals, the NCHGR will provide financial assistance for extended visits by foreign scientists in U.S. laboratories and for the purchase of equipment and supplies to enhance the collaborative projects at foreign institutions.

ELIGIBILITY REQUIREMENTS

To be eligible for an International Genome Research Collaborative Award, the following conditions must be met:

- o Only U.S. institutions where there are currently funded grants from the NCHGR are eligible to apply. The Principal Investigator (PI) of the research grant (R-series, P-series) from the NCHGR as the PI of the small grant application.
- o the U.S. applicant MUST be the Principal Investigator of an NCHGR research project grant (R or P type of awards) that has at least one remaining year of support at the time the IGRCP award is made. Since the small grant (R03) award may be up to three years in duration, it is possible for the R03 award to extend beyond the budget period of the parent grant;
- o the foreign collaborator must be a citizen of a Central or Eastern European country.
- o the foreign collaborator must demonstrate an association with an organized Human Genome Program in his/her own country; and
- o the foreign collaborator must hold a position at a public or private non-profit institution in his/her home country that will allow him/her adequate time and provide appropriate facilities to conduct the proposed research. Scientists early in their careers who have not yet achieved an independent research position are referred to the International Genome Research Fellowship Program also published in this issue of the NIH Guide for Grants and Contracts.

MECHANISM OF SUPPORT

Projects will be supported through the small grants (R03) mechanism. Grants will be awarded for a minimum of one and a maximum of three years. These awards will provide the following:

- o up to \$20,000 per year in direct cost to be used for materials, supplies, and equipment to support genomic research in the foreign laboratory or the work of the foreign collaborator while in the U.S. sponsor's laboratory;
- o a maximum of \$24,000 per annum in living expenses to support the stay of the foreign collaborator in the U.S. laboratory. The foreign collaborator must be prepared to spend a minimum of 6 continuous months in a U.S. laboratory during the period of the grant, however, 12 months is desirable for applications exceeding one year. Living expenses will be prorated at the rate of \$2,000 per month; and
- o travel expenses for the U.S. and foreign collaborators. It is desirable that once the foreign collaborator returns to his/her institution that there will be at least one reciprocal laboratory visit per year by the U.S. and foreign collaborators for the duration of the award.

All requests for funds must be adequately justified in the application by the scientific needs of the project proposed. No salaries or stipends for any of the collaborators, students, or technical assistants will be supported under these awards.

A foreign collaborator may request support to conduct research not already being supported by the U.S. investigator's parent grant; however, the research project must be an extension of or related to the currently funded research project.

The U.S. institution will have fiscal responsibility for the award. Indirect costs will be calculated on the basis of the off-site rate of the sponsoring U.S. institution. The small grant award is non-renewable and the NCHGR is under no obligation to continue support of this research either as an independent foreign grant or as a component of a recompeting parent grant.

RESEARCH OBJECTIVES

It is the intent of this collaborative program to facilitate progress on technology development, mapping, and sequencing in support of the international Human Genome Project. Applications are encouraged in the following areas:

- o construction of high-resolution genetic maps comprised of DNA markers with an average spacing of 2 centimorgans and gaps no greater than 5 centimorgans each identified by a "sequence-tagged site;"
- o construction of high-resolution physical maps of chromosomes in which contigs of at least 2 million base pairs are unambiguously ordered and identified by "sequence-tagged sites" spaced about 100,000 base pairs apart;
- o development of new and/or improvement of existing methods for DNA sequencing that are capable of significantly reducing the cost of sequencing;
- o development of computer tools, information systems, and strategies for collecting, storing, retrieving, analyzing, interpreting, and distributing large amounts of mapping and sequencing data; and
- o technology development to support all of the above objectives.

APPLICATION PROCEDURES

The application must include a letter from the foreign collaborator's responsible institutional official documenting the institution's commitment to the collaboration. The application must demonstrate that the proposed collaboration will enhance the scientific contributions of both U.S. and foreign scientists AND further the goals of the Human Genome Project, which is an international undertaking. Applications are to be submitted by the U.S. Principal Investigators on standard form PHS 398 (rev. 9/91), that is available from most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, NIH, Bethesda, MD 20892, telephone (301) 496-7441. Special application instructions are necessary and are available from the International Research and Awards Branch, Fogarty International Center (See INQUIRIES). The application consists of a section to be completed by the U.S. Principal Investigator and a separate section to be completed by the foreign collaborator. Both sections must be submitted to the NIH by the U.S. applicant organization as a single package. The number and title of this announcement must be typed in item number 2a on the face page of the PHS 398 application form. The completed original application and three legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

In addition, to expedite the review process, it is important to submit two copies of the application to:

IRAB - HG
Fogarty International Center
National Institutes of Health
Building 31, Room B2C39
Bethesda, MD 20892

If applicable, provisions for protection of human research subjects and laboratory animals must be met in both domestic and foreign settings. See Title 45 CFR Part 46 for information concerning the Department of Health and Human Services regulations for the protection of human subjects and the PHS Policy on Humane Care and Use of Laboratory Animals. These are available from the Office of Protection from Research Risks, National Institutes of Health, Building 31, Room 5B59, Bethesda, MD 20892. Information on these assurances is included in the special application instructions.

Receipt dates for completed applications are June 1, October 1, and February 1. If the deadline falls on a weekend or holiday, it is automatically extended to the next working day.

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. The application will be reviewed for scientific and technical merit by a review group of the relevant institute, center, or division. Applications in response to this program announcement will be reviewed in accordance with the usual NIH peer review procedures. The review criteria are:

- o originality of the approach;
- o soundness of the experimental design;
- o evidence that this proposed research will extend or enhance the work currently supported on the parent grant;
- o resources and environment of the U.S. and foreign collaborators; and
- o appropriateness of the budget.

Following scientific-technical review, the application will receive a second-level review by the National Advisory Council for Human Genome Research or another advisory council or board. For successful applications, awards will be made approximately ten months following receipt of applications.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following criteria will be considered in making funding decisions:

- o quality of the proposed project as determined by peer review;
- o balance among research areas; and
- o availability of funds.

The following additional criteria will be used by the NCHGR in making award decisions:

- o potential for developing technology or strategies for accelerating progress in mapping and sequencing the genomes of human and select model organisms;
- o value of the research for achieving the goals of the NCHGR;
- o potential of this collaboration to accelerate progress on the Human Genome Project;
- o demonstrated background and commitment of the U.S. and foreign investigators to further the goals of the Human Genome Project; and
- o adequacy of any plans proposed for managing data and sharing data and resources in a timely manner.

INQUIRIES

To obtain further information on this program and to request the necessary special application instructions, contact:

Dr. David A. Wolff
International Research and Awards Branch
Fogarty International Center
Building 31, Room B2C39
Bethesda, MD 20892
Telephone: (301) 496-1653
FAX: (301) 402-0779

For information on the Human Genome Program, contact:

For scientific programmatic information:

Bettie J. Graham, Ph.D.
Chief, Research Grants Branch
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
E-MAIL: B2G@CU.NIH.GOV

For grants management and fiscal matters:

Ms. Alice Thomas
Chief, Grants and Contracts Management Branch
National Center for Human Genome Research
Building 38A, Room 613
Bethesda, MD 20892
Telephone: (301) 402-0733
E-Mail: AT3@CU.NIH.GOV

The program and grants management officials welcome the opportunity to discuss any issues or questions regarding this program announcement.

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.172. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

INTERNATIONAL GENOME RESEARCH FELLOWSHIP PROGRAM FOR CENTRAL AND EASTERN EUROPE

NIH GUIDE, Volume 21, Number 14, April 10, 1992

PA NUMBER: PA-92-68

P.T. 34; K.W. 1215018, 0755045, 1004008

National Center for Human Genome Research
Fogarty International Center

PURPOSE

The purpose of the International Genome Research Fellowship Program is to provide opportunities for Central and Eastern European scientists who are in the formative stages of their research careers to obtain further training in U.S. laboratories, to exchange ideas and information about the latest advances in mapping and sequencing technology, and to improve the research potential of the fellow's home institution to pursue genomic research. For the purposes of this program, Central and Eastern Europe is defined as Bulgaria, the Czech and Slovak Federal Republic, Hungary, Estonia, Latvia, Lithuania, Poland, Romania, all republics of the (former) U.S.S.R., and Yugoslavia.

ELIGIBILITY REQUIREMENTS

To be eligible for an International Genome Research Fellowship, the applicant must:

- o be a citizen of a Central or Eastern European country;
- o have a Ph.D., M.D., or equivalent degree and no more than 10 years of postdoctoral experience in genetics, molecular biology, or other discipline that can be applied to genome research such as computer sciences, chemistry, physics, mathematics, or engineering;
- o have demonstrated an ability to engage in research;
- o have assurance of a position to which he/she can return on completion of the fellowship;
- o be proficient in the English language; and
- o obtain an invitation to work with a U.S. scientist who will act as collaborator and host.

MECHANISM OF SUPPORT

Fellowships will be supported through the International Research Fellowship (F05) mechanism. The minimum award period is 12 months and the maximum award period is 24 months. Fellowships will be awarded for a period of 12 to 24 months in the U.S. The fellowship provides:

- o Living Allowance: The fellowship does not provide for a salary or stipend; instead, awardees will receive a living allowance of \$2,000 per month while in the U.S. to cover the cost of housing and meals;
- o Travel: Round-trip fare, economy class between the fellow's home and the fellowship site on a U.S. air carrier; and
- o Institutional Allowance: The award will provide an institutional allowance of \$1,200 per month to the U.S. host institution to cover the cost of health insurance and research supplies.

RESEARCH OBJECTIVES

This fellowship program has been developed to facilitate research on the Human Genome Project, an international program to map and sequence the genomes of humans and other model organisms. Fellowship applications are

encouraged in the following areas:

- o construction of high-resolution genetic maps, comprised of DNA markers with an average spacing of 2 centimorgans, and gaps no greater than 5 centimorgans, each identified by a "sequence-tagged site;"
- o construction of high-resolution physical maps of chromosomes in which contigs of at least 2 million base pairs are unambiguously ordered and identified by "sequence-tagged sites," spaced about 100,000 base pairs apart;
- o development of new and/or improvement of existing methods for DNA sequencing that are capable of significantly reducing the cost of sequencing;
- o development of computer tools, information systems, and strategies for collecting, storing, retrieving, analyzing, interpreting and distributing large amounts of mapping and sequencing data; and
- o technology development to support all of the above objectives.

The program is open to scientists early in their careers. More established scientists are referred to the International Genome Research Collaborative Program.

Prospective applicants and U.S. sponsors must have a clear understanding about the goals of the fellowship and the specific genome research project to be pursued. Fellowship recipients will be expected to bring to the U.S. sponsor's institution the knowledge, professional background, and intellectual commitment that will make the fellowship a mutually enriching experience for the fellow and the U.S. host.

APPLICATION PROCEDURE

Prospective applicants must make applications through the U.S. institutions of the sponsors. Special application kits must be obtained from the Fogarty International Center (See INQUIRIES). A prospective applicant must:

- o describe the benefits of the fellowship to the applicant, the U.S. host, and the foreign applicant's institution;
- o describe how the fellowship will enhance the applicant's ability to pursue genomic research upon return to the home institution;
- o include a letter of invitation from the U.S. sponsor and the sponsor's portion of the application completed by the U.S. host; and
- o the application must be submitted through the U.S. institution of the sponsor.

Receipt date(s) for completed applications are September 10, January 10, and May 10 of each year.

Completed applications must be addressed to:

IRAB - IGRF
Fogarty International Center
National Institutes of Health
Building 31, Room B2C39
Bethesda, MD 20892

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. All fellowship applications will be reviewed for scientific and technical merit in accordance with the standard NIH peer review procedures. The following review criteria will be used:

- o Scientific merit of the research to be undertaken by the fellow under the guidance of the sponsor;
- o relevance of the proposed research to biomedical problems;
- o adequacy of the educational background and research experience of the applicant to undertake the proposed research;
- o whether or not the proposed research can be completed within the fellowship period;
- o the institutional environment in which the research will be carried out;
- o the compatibility of the objectives stated by the applicant and those envisaged by the sponsor; and
- o whether or not the proposed research will provide a significant expansion in knowledge beyond what the applicant is obtaining if he or she is already working in a U.S. institution.

The second level of review will be performed by the appropriate NIH funding component.

AWARD CRITERIA

For applications assigned to the National Center for Human Genome Research (NCHGR), the following criteria will be considered in making funding decisions:

- o the relevance of this training program to the goals of the Human Genome Program;
- o the quality of the training experience as determined by peer review;
- o potential of this collaboration to accelerate progress on the Human Genome Project;
- o availability of funds; and
- o if appropriate, the protections accorded human subjects and vertebrate animals and the appropriate inclusion of minorities and women if clinical studies are to be awarded.

Applicants will be notified of their status in writing approximately eight weeks following the initial review of applications and the awards will be issued by the appropriate NIH funding component. On receipt of the Notice of Research Fellowship Award, the fellowship may be activated within six months of the award date.

INQUIRIES

Inquiries about this fellowship and requests for application kits must be directed to:

Dr. David A. Wolff
International Genomic Research Fellowship Program
International Research and Awards Branch
Fogarty International Center
Building 31, Room B2C39
Bethesda, MD 20892
USA
Telephone: (301) 496-1653
FAX: (301) 402-0779

For information on the Human Genome Program, contact:

Bettie J. Graham, Ph.D.
Chief, Research Grants Branch
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
E-MAIL: B2GACU.NIH.GOV

For grants management and fiscal matters, contact:

Ms. Alice Thomas
Chief, Grants and Contracts Management Branch
National Center for Human Genome Research
Building 38A, Room 613
Bethesda, MD 20892
Telephone: (301) 402-0733
E-Mail: AT3ACU.NIH.GOV

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.172. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ERRATUM

CAUSES AND EFFECTS OF ELDERLY POPULATION CONCENTRATIONS

NIH GUIDE, Volume 21, Number 14, April 10, 1992

PA NUMBER: PA-92-62

P.T. 34; K.W. 0413001, 0710010, 0408006

National Institute on Aging
Agency for Health Care Policy and Research

This program announcement was published in the NIH Guide for Grants and Contracts on March 26, 1992, Vol. 21, No. 12, Part II of II. This erratum is to correct the following sections, which are repeated in their entirety. In addition, this program announcement will not support Career Development Awards.

ELIGIBILITY REQUIREMENTS

Applicants for research grants may be made by public and private, for-profit and non-profit organizations, such as universities college, hospitals, and laboratories. Women and minority investigators, in particular, are encouraged to apply. Foreign institutes are welcome to apply, but are advised to consult NIA staff before

applying and are strongly encouraged to apply in collaboration with a U.S. institution. Foreign institutions are only eligible for the research (R01) and conference grant (R13) mechanisms. Applicants for fellowships (F32, F33) must either be U.S. citizens or U.S. permanent residents.

REVIEW PROCEDURES

Applications will be reviewed for scientific and technical merit in accordance with established PHS review procedures. Secondary review will be by the appropriate national advisory committee.

INQUIRIES

For substantive issues and to obtain information on research resources, contact



3 1496 00509 1965

Behavioral and Social Research Program
National Institute on Aging
Gateway Building, Room 2C-234
Bethesda, MD 20892
Telephone: (301) 496-3136

Division of Primary Care
Center for General Health Services Extramural Research
Agency for Health Care Policy and Research
2102 E. Jefferson Street, Suite 502
Rockville, MD 20852
Telephone: (301) 227-8357

THE STUDY OF PATIENT OUTCOMES ASSOCIATED WITH PHARMACEUTICAL THERAPY

NIH GUIDE, Volume 21, Number 14, April 10, 1992

RFA: HS-92-03

P.T. 34; K.W. 0745005, 0795005

Agency for Health Care Policy and Research

Application Receipt Date: July 15, 1992

This Request for Applications (RFA) was published in the NIH Guide for Grants and Contracts on March 26, 1992, Vol. 21, No. 12, Part I of II. The following information was omitted from the notice of availability of RFA: "To request copies of the RFA, call (800) 358-9295."

INQUIRIES

Written and telephone requests for and inquiries concerning this RFA are encouraged.

Direct inquiries regarding programmatic issues to:

Lynn Bosco, M.D. or Eleanor M. Perfetto, Ph.D.
Center for Medical Effectiveness Research
Agency for Health Care Policy and Research
2101 E. Jefferson Street, Suite 605
Rockville, MD 20852
Telephone: (301) 227-8485

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

5333 Westbard Avenue
Bethesda, MD 20816

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For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21., No. 15
April 17, 1992

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NOTICES OF AVAILABILITY (RFPs AND RFAs)

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This publication is also available electronically to institutions via BITNET or INTERNET. Alternative access is through the NIH Grant Line using a personal computer. Contact Dr. John James at 301/496-7554 for details, or send an E-mail message to ZNS@NIHCU.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

VANGUARD CLINICAL CENTERS FOR THE CLINICAL TRIAL AND OBSERVATIONAL STUDY OF THE WOMEN'S HEALTH INITIATIVE

NIH GUIDE, Volume 21, Number 15, April 17, 1992

RFP AVAILABLE: NIH-WH-92-19

P.T. 34, II; K.W. 0755015, 0760025, 0411005, 0715035, 0715040, 0705050

National Institutes of Health

The National Institutes of Health seeks approximately 15 Vanguard Clinical Centers for the Clinical Trial (CT) and Observational Study (OS) components of the Women's Health Initiative.

CT objectives are to test the benefits and risks of hormone replacement therapy, dietary modification, and supplementation with calcium plus Vitamin D on the overall health of U.S. post-menopausal women ages 50-79. Approximately 57,000 women will participate in the various components of the Clinical Trial.

OS goals are to: (1) improve risk prediction of coronary heart disease, breast cancer, fractures, and total mortality in postmenopausal women; (2) examine the impact of "spontaneous" changes in characteristics on disease and total mortality; and (3) create a resource of data and biologic samples that can be used to unearth new risk factors and/or biomarkers for disease. The OS cohort will comprise approximately 100,000 U.S. women.

The Vanguard Clinical Centers shall cooperate with a Clinical Coordinating Center in developing, testing, and refining the overall program and in writing the final protocol, Manual of Operations, and training materials before recruitment commences in the approximately 15 Vanguard Centers and in approximately 30 additional Clinical Centers. A separate solicitation will be issued at a later date for these additional Clinical Centers. Each Vanguard Clinical Center shall be responsible for screening, recruitment, randomization, and follow-up of approximately 1,270 CT participants and 2,222 OS participants (with a minimum of 1,000 CT and 2,000 OS).

This is not a Request for Proposals (RFP). RFP NIH-WH-92-19 will be available on or about April 20. Proposals will be due on or about June 15, 1992. All responsible sources may submit a proposal that will be considered. No collect calls will be accepted.

A copy of RFP NIH-WH-92-19 may be obtained by written request, including two self-addressed mailing labels, to:

National Institutes of Health
W.H.I., Research Contracts Branch, DCG
Federal Building, Room 1C11
Bethesda, MD 20892

MASTER AGREEMENTS FOR LARGE-SCALE ISOLATION OF ANTITUMOR AND ANTI-AIDS AGENTS FROM NATURAL SOURCES

NIH GUIDE, Volume 21, Number 15, April 17, 1992

RFP AVAILABLE: NCI-CM-37814-30

P.T. 34; K.W. 0740012, 0740020, 0750025

National Cancer Institute

The National Cancer Institute (NCI), Division of Cancer Treatment (DCT), Development Therapeutics Program (DTP), National Institutes of Health (NIH), is interested in receiving proposals from, and establishing Master Agreements with, offerors with the capability to: (1) extract bulk plant, animal, and microbial materials to provide primary extracts; and/or (2) isolate and purify natural products from primary extracts of plant, animal, and microbial materials on a pilot plant scale. Two separate work areas are available for offerors. Separate proposals will be required from offerors responding to both work areas. The Government will supply the plant, animal, or microbial material to be processed and details of the known isolation processes. The successful offerors will supply all equipment, solvents, reagents, and other materials needed for the project.

WORK AREA NO. 1

Offerors must provide equipment to grind and extract a variety of natural products in quantities ranging from 50 kg to 10,000 kg of bulk crude materials. This includes frozen storage capabilities for up to 1,000 kg of marine materials and equipment for the safe, non-destructive removal of extraction solvents. The Government will supply the plant, animal, or microbial material to be processed. The experience and ingenuity of the offerors' process development for pilot plant extractions and isolations using standard or novel techniques will be important factors in the evaluation of the proposals.

WORK AREA NO. 2

Offerors must provide equipment for large-scale isolation and purification of natural products, and have refrigerated storage capacity for up to 750 gallons of primary extract. The agents isolated must be high purity, suitable for subsequent manufacture of clinical dose forms, and all work must be carried out in compliance with the Food and Drug Administration Current Good Manufacturing Practices (FDA-CGMP). A requirement is that the contractor's facilities must be in compliance with FDA-CGMP regulations at the time a Master Agreement Order is awarded under the Master Agreement. The experience and ingenuity of the offerors in process development for pilot plant extractions and isolations using standard or novel techniques will be important factors in the evaluation of the proposals.

It is anticipated that multiple Master Agreement Awards will be made. The Request for Proposal (RFP) will be issued on or about April 22, 1992. Each Master Agreement Award is anticipated for a five-year period, beginning approximately April 30, 1993. Address requests for the RFP to:

Elsa B. Carlton
Contract Specialist
Treatment Contracts Section
National Cancer Institute
Executive Plaza South, Room 604
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-8620

No collect calls will be accepted.

SMALL GRANTS PROGRAM FOR NURSING AND BIOLOGY INTERFACE

NIH GUIDE, Volume 21, Number 15, April 17, 1992

RFA AVAILABLE: NR-92-04

P.T. 34; K.W. 0785130, 0710095, 1215015, 1002024, 1002008, 0710030

National Center for Nursing Research

Letter of Intent Receipt Date: June 1, 1992
Application Receipt Date: August 24, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES.

PURPOSE

The small grants program of the National Center for Nursing Research provides limited support for meritorious research to develop and test innovative biological techniques for solving nursing problems and answering nursing clinical questions.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Small Grants for Program Nursing and Biology Interface, is related to the priority area of physical activity, nutrition, and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00473-1) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

The innovative biological technique proposed must be an integral part of an ongoing NIH or extramurally funded research program designed by a nurse biological scientist or a nurse scientist in collaboration with a biological scientist. The Small Grants Program should result in novel preliminary data using state-of-the-science bioinstrumentation or biological technology that would strengthen a subsequent research (R01) application.

As Principal Investigator, it is preferred that the nurse applicant: (1) be actively engaged in biological or biobehavioral research with previous or current NIH or other extramural funding and (2) have formal or the equivalent of postdoctoral experience in the biological or biobehavioral topic under investigation.

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from women and minority individuals are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institute of Health (NIH) small grants (R03) program mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement (October 1, 1990). The NCNR may reissue this RFA in fiscal year 1993.

FUNDS AVAILABLE

It is estimated that \$250,000 will be committed to fund applications submitted in response to this RFA. It is expected that five applications will be funded. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit and the availability of funds. Each grant is limited to \$50,000 in total project costs. The project period may be up to two years. A small grants program award is nonrenewable.

RESEARCH OBJECTIVES

This RFA has two distinct aims: (1) to stimulate nurse investigators to explore innovative, state-of-the-science research using biological technology, if the successful outcome of such research would rapidly advance the following nursing research areas: studies linking basic biological sciences with (a) nursing clinical questions and (b) nursing studies having a biological focus, and (2) to facilitate use of state-of-the-science

biological techniques by nurse researchers. The validation of nursing practice by the application of biological science into nursing research requires investigators to have the ability to use new techniques of structural and molecular biology, genetics, biophysics, and immunology. This program will facilitate translation of basic scientific technology into a basis for future measurements in nursing research.

Illustrative biotechnology and topic examples:

Biotechnology: recombinant DNA, gene mapping and/or sequencing, signal transduction, crystallographic analysis, peptide/protein modeling and molecular dynamics simulation, in vitro or in vivo nuclear magnetic resonance spectroscopy or imaging, positron emission tomography, isotopic scanning, monoclonal antibodies, high pressure liquid/gas chromatography, and spectrophotometry.

Topics:

o A nurse scientist whose research is interventions to treat pain might be interested in measuring gene expression in the dorsal root ganglia, in which the amount of messenger RNA changes after tissue and nerve injury.

o A nurse scientist whose research is interventions to treat and prevent lead poisoning in school age children might be interested in identifying blood cell markers as an immunological component of the health assessment in this population. The biotechnology might include biological and biochemical cellular markers to identify lead poisoning.

o A nurse scientist whose basic science research involves identifying homeostatic mechanisms for regulating calcium ion concentration in cardiac cells might choose to study the control of ionic flux in the degeneration of cell function.

o A nurse scientist whose clinical research is symptom management of complications arising from type II diabetes and obesity might be interested in the biochemical characterization of insulin resistance seen in these disorders. Working with a molecular biologist in the laboratory, the purpose of the R03 application might be to study an aspect of insulin function at the molecular level.

o A nurse scientist whose clinical research is the quality of life after organ transplantation might be interested in evaluating immunologic indices of patient outcomes after bone marrow transplants. Collaborating with an immunologist in the laboratory, the purpose of the R03 application might be to study monoclonal antibodies produced by hybridomas in bone marrow transplants.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit by June 1, 1992, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NCNR staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Ethel B. Jackson, D.D.S.
Chief, Office of Scientific Review
National Center for Nursing Research
Building 31, Room 5B19
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-0472
FAX: (301) 480-4969

APPLICATION PROCEDURES

The application receipt date is August 24, 1992. The research grant application form PHS 398 (rev. 9/91) is to be used. These forms are available at most institutional business offices and the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/496-7441.

The following supplemental instructions are given: (1) Background and Significance: The applicant must be explicit in describing the interface of the chosen biological technique with clinical nursing research questions. (2) Progress Report/Preliminary Studies: Since this award mechanism intends to fund innovative use of technology, preliminary data are not required. (3) The entire application is limited to 15 pages. (4) Do not submit an Appendix.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. Those applications that are complete and responsive will be evaluated for scientific/technical merit by an appropriate special review group organized by the NCNR. The second level of review will be provided by the NCNR advisory council.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct inquiries regarding programmatic issues to:

Hilary D. Sigmon, Ph.D., R.N.
Nurse/Health Scientist Administrator
National Center for Nursing Research
Westwood Building, Room 754
Bethesda, MD 20892
Telephone: (301) 496-0523

Direct inquiries regarding fiscal matters to:

Sally A. Nichols
Grants Management Officer
National Center for Nursing Research
Westwood Building, Room 748
Bethesda, MD 20892
Telephone: (301) 496-0237

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.336, Nursing Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

PHYSICIAN AND SCIENTIST TRAINING PROGRAM IN UROLOGIC RESEARCH

NIH GUIDE, Volume 21, Number 15, April 17, 1992

RFA AVAILABLE: DK-92-05

P.T. 44; K.W. 0785220, 0715167, 0715105, 0715026, 0765035

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: June 1, 1992
Application Receipt Date: August 6, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACTS NAMED IN "INQUIRIES," BELOW.

PURPOSE

The Division of Kidney, Urologic and Hematologic Diseases (DKUHD) of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), in cooperation with the American Foundation for Urologic Diseases (AFUD), invites applications for a pilot fundamental research training program in urologic sciences. Proposed programs are expected to provide postdoctoral research training in the basic biological sciences related to the urologic disorders of interest to the NIDDK.

Each program will provide research training both for physicians who have completed at least two years of surgical training in urology and for individuals holding the Ph.D. degree trained in basic science. The total program in an awardee institution will be supported by two separate but linked awards from the NIDDK and coordinated support from the AFUD. Research training for physicians with clinical training in urology will be supported through a Program Physician Scientist Award (K12) and post-Ph.D. research training in urologically related problems will be supported by a National Research Service Award (NRSA) Institutional Training Award (T32). The AFUD will provide supplementation to the stipends of the Ph.D. trainees supported by the T32 and the salaries of the M.D.s supported by the K12 according to the schedule given in the RFA.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Physician and Scientist Training Program in Urologic Research, is related to the priority area of diabetes and chronic disabling diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00473-1) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

The grantee institution must be a domestic university, medical school, or comparable institution with a strong, well-established program of research and training in areas related to urologic disease. To qualify for a K12 award, an institution must have an adequate number of highly trained faculty in clinical and basic science disciplines as well as the interest, capability, and commitment to provide guidance to clinically trained investigators in developing research independence.

MECHANISM OF SUPPORT

The training programs will combine two NIH award mechanisms, the K12 and the T32. The AFUD will make separate awards to those institutions holding the K12/T32 awards to supplement the salaries (K12 participants) and stipends (T32 participants).

Responsibility for the planning, direction and execution of the proposed program will be solely that of the applicant. The total project period for applications is five years. The anticipated award date is July 1, 1993.

FUNDS AVAILABLE

This program will support up to five institutions for a total funding of five T32 awards and five K12 awards. The number of awards made will depend on receipt of a sufficient number of applications of high scientific merit. Up to \$600,000 (total costs) will be allocated to the support of this program in FY 1993, availability of funds permitting.

RESEARCH OBJECTIVES

The urologic diseases affect a significant portion of both the pediatric and adult populations. Progress in the understanding and treatment of these diseases is hampered by lack of a sufficient number of research scientists and research clinicians in these areas. Surveys have suggested that the combination of the long period of residency training required for board certification in Urology and the low stipends awarded for support in NRSA training programs constitute a major obstacle to recruiting and training urologists for research careers. To facilitate the recruitment of individuals into research training programs in urologic diseases, the DKUHD and the AFUD have developed a joint program to supplement the NIH support with designated funds from the AFUD.

Areas for research training within this program are limited to those that fall within the primary responsibility of the NIDDK. These areas are broadly defined as: prostate growth control; prostate development including benign prostatic hyperplasia (BPH); chronic inflammatory urologic disorders such as prostatitis and interstitial cystitis; the basic science and clinical aspects of urolithiasis; physiology and pathophysiology of bladder function including voiding dysfunctions such as urinary incontinence, enuresis and vesicoureteral reflux; infections of the urinary tract; male sexual function and dysfunction including the basic aspects of testicular

and epididymal function; and pediatric urology. Institutions, program directors, and individual applicants should contact the appropriate staff at the NIDDK to ensure that the research areas of the proposed research training fall within the purview of the NIDDK.

Candidates for the K12 must hold the M.D. or equivalent degree (e.g., D.O.), must have completed the general surgery requirement for urology, and should have two years of urologic surgery training. K12 participants are expected to spend a total of at least five years in the research training experience.

Holders of the Ph.D. and other research degrees will be considered candidates for support under the T32. The emphasis of the T32 will be to support specialized training in the basic sciences relevant to the study of the genitourinary tract and urologic disorders and diseases.

The proposed Program Director must be designated as Program Director on both the T32 and K12 applications. He/she should be able to demonstrate scientific expertise, leadership, and the administrative ability to coordinate and supervise an interdisciplinary research program of this scope.

SPECIAL REQUIREMENTS

Applications must meet all NIH requirements for the T32 and K12 awards. Applications may request funding for five years; however, applicants should note that the training periods for physicians supported by this program will generally cover a total of six calendar years for each participant, including one of clinical work not supported by this program. In the event that a K12 award is not competitively renewed at the end of the initial five-year project period, it is the intention of the NIDDK, availability of funds permitting, to support the completion of each enrolled participant's program under an extension of the original terms of the award.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 1, 1992, a letter of intent that includes a descriptive title of the proposed program, the name, address and telephone number of the Program Director, the identities of other key personnel and participating institutions, and the number and title of this RFA.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. The letter of intent is to be sent to:

Dr. Robert D. Hammond
Chief Review Branch
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 603
Bethesda, MD 20892
FAX: (301) 402-1277

APPLICATION PROCEDURES

Each training institution will submit a K12 application and a T32 application. An applicant institution will receive both awards or neither. Holding both a K12 and a T32 will enable each grantee institution to train both physicians (supported by the K12) and Ph.D. degree holders (supported by the T32).

Separate T32 and K12 applications are to be submitted on form PHS 398 (rev. 9/91) following the guidelines for each specific type of award. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/496-7441; and from the program administrators named under INQUIRIES below.

Applications must be received no later than August 6, 1992.

REVIEW CONSIDERATIONS

Applications will undergo an initial review by an NIDDK Initial Review Group. The T32 and K12 applications will be reviewed according to the established review criteria that are described in the announcement "National

Research Service Awards for Institutional Training Grants (T32): Information Statement, October 1, 1990," and in the "K Awards." Both documents may be obtained from the staff listed under INQUIRIES. In addition, the T32 and K12 applications from a given institution will be reviewed together to evaluate the proposed integration and overall quality of potential research experiences for preparing clinical and basic scientists to undertake careers in all areas of urologic research supported by the NIDDK.

Subsequent to review by the Initial Review Group, applications will be reviewed by the NIDDK National Advisory Council.

INQUIRIES

It is essential that prospective applicants receive a copy of the RFA before developing an application. The RFA and other information may be obtained from:

Leroy M. Nyberg, Jr., Ph.D., M.D.
Director, Urology Program
or
Charles H. Rodgers, Ph.D.
Director, Manpower and Training Programs
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A-05
Bethesda, MD 20892
Telephone: (301) 496-7133
FAX: (301) 402-0223

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.849. Awards are made under authorization of the Public Health Service Act, title IV, part A (Public Law 78-410), as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

CLINICAL CANCER THERAPY RESEARCH

NIH GUIDE, Volume 21, Number 15, April 17, 1992

PA NUMBER: PA-92-69

P.T. 34; K.W. 0715035, 0785035, 0745005, 0745070, 0710045, 0710100

National Cancer Institute

PURPOSE

The National Cancer Institute (NCI) seeks grant applications to conduct clinical therapeutic studies of neoplastic diseases in humans. Clinical research, by definition, involves a clinician/patient-subject interaction with a therapeutic intent. This Program Announcement (PA) encompasses a full range of therapeutic studies and clinical trials employing drugs, biologics, radiation, and surgery. The intent of the announcement is to encourage clinical researchers to translate insights in cancer biology and the development of new agents into innovative cancer therapeutic studies.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Clinical Cancer Therapy Research, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments and

eligible agencies of the Federal government. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) Award (R29). Applications from minority individuals and women are encouraged. An application may include one or more institutions (e.g., individual institutions, consortia, cancer centers) with established clinical, laboratory, and statistical resources.

MECHANISM OF SUPPORT

Awards will be made as investigator-initiated research grants (R29, R01 and interactive R01s) through the National Institutes of Health (NIH) grant-in-aid, in accordance with PHS policies applicable to research project grants. This latter mechanism is used when the NCI wishes to stimulate investigator-initiated research projects in areas of special interest to the National Cancer Program. A description of an interactive R01 application can be found in the NIH Guide for Grants and Contracts (Vol. 21, No. 1, January 10, 1992) under PA-92-29. The special eligibility criteria for the FIRST Award (R29) can be found in the Guidelines for FIRST AWARD (version February 1991), which may be obtained from the Grants Inquiries Office, Division of Research Grants, NIH. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 82-50,000, revised January 1, 1987.

RESEARCH OBJECTIVES

Summary

In the past several years, the research effort into understanding the basic biology of the cancer cell has been highly productive. Recent discoveries concerning the role of growth factors, genes that promote and suppress neoplasia, mechanisms of treatment sensitivity and resistance, and the biology of the immune systems have provided the basis for the development of novel and improved cancer treatments. The rate of progress in the treatment of cancer will depend upon the translation of these basic and preclinical discoveries into clinical cancer therapies. The NCI supports an extensive network of clinical and laboratory research studies related to cancer therapy through contracts, grants, and cooperative agreements. At present, the traditional research grant mechanism (R01, R29) is underutilized by clinical investigators for the support of clinical research. The Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment, NCI, the program primarily responsible for the promotion and translation of new basic and preclinical research into therapeutic advances, receives relatively few research grant applications. Whereas a Request for Applications (RFA) represents a single solicitation, a PA provides the opportunity for the receipt of new applications on a continuing basis. NCI encourages clinical investigators to submit clinical therapeutic studies and is committed to moving advances in basic biology and drug development into the clinical setting.

Clinical studies must involve human subjects and be designed to ultimately improve cancer treatment. The applications may include single or multi-institutional research studies with appropriate biological correlates linked to these studies. New clinical therapeutic studies may employ drugs, biologics, radiation, or surgery used as single agents/modalities or in combination. Biological correlative studies that have clinical relevance to cancer therapies and are aimed at improving cancer treatment are also appropriate.

Some examples of clinical therapeutic studies include: (1) therapies based on novel mechanisms of action, mechanism of action and metabolic studies of antitumor agents; (2) studies of mechanisms of hormone-, drug-, or radiation-resistance and reversal; (3) mechanism of action of biological response modifiers in the treatment of cancer, e.g., cancer immunotherapy (monoclonal antibodies, cytokines, antisense, and vaccines) alone or in combination with chemotherapeutic agents; (4) mechanism of action of new growth factor targeted therapies; (5) new radiation therapies or radiation modifiers to enhance cell kill or protect normal tissue; (6) surgical therapies in combination with therapeutic agents.

Some examples of biological correlative studies include: (1) phenotypic or genotypic alterations that appear to correlate with the development of drug-, hormone-, or radiation-resistance; (2) oncogenes, growth factors, and specific antigen expression on tumor cells; (3) pharmacokinetic and pharmacodynamic measurements; (4) biochemical pharmacologic parameters; (5) imaging studies to assess efficacy of treatment.

Investigators are not limited to the above areas of potential studies. Clinical research, by definition, must involve a clinician/patient-subject interaction with a therapeutic intent.

Objectives

The aims of this initiative are two-fold: (1) to support innovative correlative laboratory studies relevant to therapeutic clinical trials and (2) to stimulate development of innovative therapeutic clinical studies with laboratory correlations to foster the development of interactions between basic science laboratories and clinicians performing these clinical trials.

STUDY POPULATION

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF FEMALES AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, 1-4 of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the deadlines indicated in the application kit (February 1, June 1, and October 1). Specific application procedures for interactive R01 applications can be found in the NIH Guide for Grants and Contracts (Vol. 21, No. 1 - January 10, 1992) under PA-92-29.

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441. The title and number of the announcement must be typed in Section 2a on the face page of the application.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources are requested to identify the GCRC as a source for conducting the proposed research. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator must be included with the application.



3 1496 00509 5826

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892 **

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications recommended for further consideration will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Roy S. Wu or Ms. Diane Bronzert
NCI Program Directors
Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

Direct inquiries regarding fiscal matters to:

Ms. Marian Focke
Grants Management Specialist
National Cancer Institute
Executive Plaza South, Room 242
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 46
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No 93.395, Cancer Treatment Research. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21., No. 16
May 1, 1992

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This publication is also available electronically to institutions via BITNET or INTERNET. Alternative access is through the NIH Grant Line using a personal computer. Contact Dr. John James at 301/496-7554 for details, or send an E-mail message to ZNS@NIHCU.

NOTICESPRINCIPAL INVESTIGATOR MAILING ADDRESSES

NIH GUIDE, Volume 21, Number 16, May 1, 1992

P.T. 34; K.W. 1014006

National Institutes of Health

Correspondence from the NIH to applicant Principal Investigators is sometimes returned to the NIH due to an insufficient address. The investigator address used by the NIH for such correspondence is taken from Item 3e of the PHS 398 application. Correspondence includes snap-out mailers with assignment information and snap-out mailers with percentile and priority score information. PI's are urged to ensure that the mailing address given

on the grant application is as specific as possible. In addition to the street, city, state, and zip code, please include any additional information that might assist in mail delivery within the institution, such as a room number, department, and/or building.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

CEREBRAL MAGNETIC RESONANCE IMAGING READING CENTER FOR THE ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

NIH GUIDE, Volume 21, Number 16, May 1, 1992

P.T. 34; K.W. 0706030, 0715042

RFP AVAILABLE: RFP-NIH-NHLBI-HC-92-21

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) requires a Reading Center to interpret cerebral magnetic resonance images (MRI) performed in the epidemiological research study of the major factors contributing to the occurrence of cardiovascular disease in middle-aged adults entitled "Atherosclerosis Risk in Communities Study (ARIC)." The MRI Reading Center will assist in protocol development for the performance of cerebral MRI on 2,000 participants at 2 of the ARIC Field Centers and will perform measurements and interpretations of these images in a standardized and reproducible manner. The period of performance is anticipated to be March 1, 1993 through February 28, 1995.

This is an announcement for a Request for Proposals (RFP). RFP NHLBI-HC-92-21 will be available on or about April 14, 1992, with proposals due June 1, 1992. One award is anticipated to be made during December 1992. Written requests must include three mailing labels, self addressed, and must cite RFP No. NHLBI-HC-92-21.

Requests for copies of the RFP are to be sent to the following address:

Donna J. Neal
Contract Specialist
ECA Section, Contracts Operations Branch, DEA
National Heart, Lung, and Blood Institute
7550 Wisconsin Avenue
Federal Building, Room 3C16
Bethesda, MD 20892

NATIONAL COLLABORATIVE RADIATION THERAPY TRIALS: 3-D DOSE ESCALATION STUDY FOR PROSTATE CANCER

NIH GUIDE, Volume 21, Number 16, May 1, 1992

RFA AVAILABLE: CA-92-05

P.T. 34; K.W. 0715035, 0705075, 0745062, 0755015

National Cancer Institute

Letter of Intent Receipt Date: June 1, 1992
Application Receipt Date: August 26, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The Radiation Research Program (RRP), Division of Cancer Treatment (DCT), of the National Cancer Institute (NCI) invites applications for cooperative agreements to carry out National Collaborative Radiation Therapy Trials: 3-D Dose Escalation Study for Prostate Cancer. The objectives of the present solicitation are (1) to conduct Phase I, II, and III clinical trials to test the efficacy of using 3D conformal radiation therapy in a dose escalation study for the treatment of prostate cancer, and (2) to collect 3-D dose distributions and data on radiation-induced damage to normal tissues.

The decade of the 1980s brought unprecedented advances in computer hardware and software for the development and implementation of 3-D techniques in radiation therapy treatment planning and treatment delivery. The new 3-D technology has the potential to deliver higher radiation doses to tumor targets with no increase in normal tissue morbidity. The potential benefit to the cancer patient is improved local control, fewer complications to normal tissues, and longer survival. A potential risk is that tight, conformal fields will underdose occult tumor at the margins of the fields.

Multi-institutional trials are supported by the NCI for the conduct of clinical trials to establish the efficacy of new therapies and new approaches for the treatment of cancer. The objective of this RFA is to support multicenter cooperative clinical trials carrying out a dose-escalation study in the treatment of prostate cancer.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, National

Collaborative Radiation Therapy Trials: 3-D Dose Escalation Study for Prostate Cancer, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged. Additional eligibility requirements for the Operations and Statistical Center and for the Radiotherapy Center are described in the RFA.

MECHANISM OF SUPPORT

Awards will be made as cooperative agreements (U01), a funding mechanism in which substantial NCI programmatic involvement with the recipients during performance of the planned activity is anticipated. Applicants will be responsible for the planning, direction, and execution of the proposed project. The total project period for applications submitted in response to the present RFA may not exceed three years. The anticipated award date will be April 1, 1993.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary NIH peer review.

FUNDS AVAILABLE

Approximately \$750,000 in total costs per year for four years will be committed to fund applications submitted in response to this RFA. The NCI anticipates a single award for funding of an Operations and Statistical Center, and up to four to five separate awards to radiotherapy centers for a period of four years. The funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of cooperative agreements in response to this RFA is also contingent upon the availability of funds for this purpose.

SPECIAL REQUIREMENTS

The administrative and funding mechanism to be used to support these awards will be a cooperative agreement (U01) between each awardee and the NCI. In a cooperative agreement there is substantial Federal programmatic involvement above and beyond the levels characteristic for traditional program management of grants. Prospective applicants are encouraged to obtain a copy of the RFA for additional information (see INQUIRIES section below).

RESEARCH OBJECTIVES

The objective of this RFA is to support multicenter cooperative clinical trials to conduct disease-specific Phase I and II studies using 3-D conformal radiotherapy (3DCRT) techniques that will define a new maximum-tolerated dose (MTD) beyond standard radiation therapy for prostate cancer treatments. Should the Phase II results be sufficiently convincing that a new MTD has been reached, the Cooperative Group will proceed to Phase III trials in which 3DCRT will be compared with best standard conventional therapy for prostate cancer. The Cooperative Group, through the Executive Committee, will also define protocols for scoring radiation injury as a function of dose and volume to the normal tissues at risk for this disease, which is to be incorporated into a new 3D database for future reference and use by scientific investigators. The design, structure, and maintenance of the 3-D database is a research objective of this RFA.

The DCT, NCI intends to support these trials by the awarding of cooperative agreements to participating institutions that have the capability of planning and delivering 3-D conformal radiation therapy and to a single organization or institution that is capable of coordinating the multi-institutional studies and serving as a data management and analysis center.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of minorities in study populations. If minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 1, 1992, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which an application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is requested in order to provide an indication of the number and scope of applications to be reviewed.

The letter of intent is to be sent to Dr. Sandra Zink at the address noted below.

APPLICATION PROCEDURES

Application for Public Health Service cooperative agreements must be submitted on form PHS 398 (rev. 9/91). Application kits are available from most institutional business offices, and may be obtained from the Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Bethesda, MD 20892, or telephone: (301) 496-7441.

Applications must be received by August 26, 1992. If an application is received after that date, it will be returned. Also, the Department of Research Grants will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH review group or awarding unit.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the DRG for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to the program requirements and criteria stated in the RFA is an NCI program staff function. Applications that are judged non-responsive will be returned to the Principal Investigator by the NCI, but may be submitted as investigator-initiated research grants. Questions concerning the responsiveness of proposed research to the RFA should be directed to program staff. Detailed review criteria are listed in the full RFA.

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of this RFA and inquires about whether or not specific proposed research would be responsive are encouraged and may be directed to Dr. Zink at the address below. Dr. Zink welcomes the opportunity to clarify any issues or questions from potential applicants.

For technical information:

Dr. Sandra Zink
Program Director, Radiation Research Program
National Cancer Institute
Executive Plaza North, Suite 800
Bethesda, MD 20892
Telephone: (301) 496-9360
FAX: (301) 480-5785

For business information:

Ms. Barbara Fisher
Grants Management Specialist
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 242
6120 Executive Boulevard
Rockville, MD 20852
Telephone: (301) 496-7800, Ext. 24
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.395, Cancer Treatment Research. Awards are made under the authorization of Public Health Service Act, Title IV, Sections 301, 410 and 411, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285 (a.)) and administered under the PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

HYPOTHESIS DRIVEN CLINICAL CORRELATIONS IN HEMATOLOGIC MALIGNANCIES

NIH GUIDE, Volume 21, Number 16, May 1, 1992

RFA AVAILABLE: CA-92-16

P.T. 34; K.W. 0715035, 0715032, 0785070, 0755018

National Cancer Institute

Letter of Intent Receipt Date: June 17, 1992
Application Receipt Date: September 16, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The Cancer Therapy Evaluation Program (CTEP) of the Division of Cancer Treatment (DCT) and the Cancer Diagnosis Branch (CDB) of the Division of Cancer Biology, Diagnosis and Centers (DCBDC) at the National Cancer Institute (NCI) invite applications for cooperative agreements from institutions or consortia, such as DCT Clinical Trials Cooperative Groups, capable of and interested in performing hypothesis driven clinical correlative studies relevant to the cancer treatment or clinical outcome of patients with hematologic malignancies. It is essential for institutions to have access to biologic samples and outcome data for a sufficient number of patients on

phase III clinical protocols to be able to test correlative hypotheses. Hematologic malignancies that are relevant to this RFA include leukemias, lymphomas, myelomas, and myelodysplastic syndromes.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Hypothesis Driven Clinical Correlative Studies in Hematologic Malignancies, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone (202) 783-3238).

ELIGIBILITY REQUIREMENTS

Domestic and foreign for-profit and not-for-profit organizations, governments and their agencies are eligible to apply. Applications from minority individuals and women are encouraged. It is essential for institutions to have access to a sufficient number of patients on phase III clinical protocols to be able to test correlative hypotheses. The Applicant Institution must have access to a Central Operations Office and a Statistical Center for coordination of research activities and data analysis.

MECHANISM OF SUPPORT

Support of this program will be through the cooperative agreement (U01), an assistance mechanism in which substantial NCI programmatic involvement with the recipients during performance of the planned activity is anticipated. The nature of NCI staff involvement is described in the RFA. Applicants will be responsible for the planning, direction, and execution of the proposed project. Except as otherwise stated in this RFA, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 90-50,000, revised October 1, 1990.

This RFA is a one-time solicitation. If it is determined that there is a sufficient continuing program need, the NCI will invite recipients of awards under this RFA to submit competitive continuation cooperative agreement applications for review according to the procedures described below.

FUNDS AVAILABLE

Approximately \$2,000,000 in total costs per year for four years will be committed to fund applications submitted in response to this RFA. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. It is anticipated that 10-12 awards will be made. The total project period for applications submitted in response to the present RFA may not exceed four years. The earliest feasible start date for the initial awards will be August 1, 1993. Although this program is provided for in the financial plans of the NCI, the award of cooperative agreements pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The objectives of this RFA are to foster collaborations and interactions between basic researchers and clinical investigators to advance therapeutic clinical research and conduct hypothesis driven correlative studies in hematologic malignancies that are ready for large scale evaluation. Hematologic malignancies relevant to this RFA account for significant cancer incidence, morbidity, and mortality. Special consideration will be given to studies with acute promyelocytic leukemia, multiple myeloma, chronic lymphocytic leukemia, acute myeloid leukemia, and acute lymphocytic leukemia. Each application is expected to be focused on a specific hematologic malignancy. Applicants may propose to undertake several correlative studies relevant to the specific hematologic malignancy during the grant funding period. An individual scientist or a consortium of institutions may be included on more than one application.

The correlative studies should be based on strong and testable hypotheses. A clear rationale should be given for the experimental design and technical methodologies selected. The hypotheses tested must relate to potential clinical applications such as development of new treatment strategies or identification of patient subsets for specific treatment approaches. Preliminary data from appropriate tumor models or analysis of patient specimens must be provided to support the feasibility of each study. This RFA is not for developing new techniques or assays. Assays must have already been demonstrated to be applicable to tissue samples and/or body fluids. The laboratory assays must utilize tumor specimens from patients receiving defined treatments in large clinical trials such as phase III clinical protocols. Applications must include a statistical section describing plans for analysis of data designed to test the hypotheses. Investigators must have access to a sufficient number of patient specimens and patient outcome data from phase III clinical trials. All investigators are encouraged to work with multi-center organizations or form a consortium of institutions in order to access a sufficient number of patients and clinical information to test the proposed hypotheses. To coordinate the above activities, each institution must have access to a Central Operations Office and Statistical Center as defined in the RFA.

The cooperative approach outlined in this RFA allows for interactions among successful applicants and is designed to optimize use of patient resources, tissues, reagents, and methods. Applicants must describe how they will interact with the NCI and other awardees in the sharing of data and improvements in laboratory techniques and study design methodologies.

SPECIAL REQUIREMENTS

The RFA describes the complete terms for this cooperative agreement including terms of cooperation, nature of participation by NCI staff, responsibilities of the awardees, and the arbitration process to resolve disputes. Special instructions for preparation of cooperative agreement applications are also included.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 17, 1992, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is requested in order to provide an indication of the number and scope of applications to be reviewed.

The letter of intent is to be sent to:

Dr. Roy S. Wu
Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

APPLICATION PROCEDURES

Applications must be received by September 16, 1992. If an application is received after that date, it will be returned. The PHS 398 research grant application form is to be used in applying for cooperative agreements. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892, telephone (301) 496-7441; and from the NCI Program Director named below.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the Division of Research Grants for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to the program requirements and criteria stated in the RFA is an NCI program staff function. Applications that are judged non-responsive will be returned to the applicant by the NCI. Questions concerning the responsiveness of proposed research to the RFA are to be directed to program staff (see INQUIRIES).

AWARD CRITERIA

The anticipated date of award is August 1, 1993. In addition to the technical merit of the application, NCI will consider how well the applicant institution met the goals and objectives of the program as described in the RFA, availability of resources, and study populations.

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of this RFA and inquires about whether or not specific proposed research would be responsive are encouraged and must be directed to Dr. Roy S. Wu or Dr. Sheila Taube at the addresses below. The NCI Program Directors welcome the opportunity to clarify any issues or questions from potential applicants.

For technical information:

Dr. Roy S. Wu
Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

or

Dr. Sheila E. Taube
Diagnosis Branch/DCBDC
National Cancer Institute
Executive Plaza South, Room 638
Bethesda, MD 20892
Telephone: (301) 496-1591
FAX: (301) 402-1037

For business information:

Ms. Mable Lam
Grants Management Specialist
National Cancer Institute
Executive Plaza South, Room 242
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 48
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No 93.395, Cancer Treatment Research. Awards are made under the authorization of the Public Health Service Act, Title IV Sections 301, 410, and 411, Part A (Public Law 78-410, 42 USC 241 as amended, Public Law 99-158, 42 USC 285a) and administered under PHS grant policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

TREATMENT OF BENIGN PROSTATIC HYPERPLASIA: PILOT STUDY

NIH GUIDE, Volume 21, Number 16, May 1, 1992

RFA AVAILABLE: DK-92-18

P.T. 34; K.W. 0715105, 0705075, 0755015, 0755018, 0740020

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: June 2, 1992
Application Receipt Date: June 17, 1992

THE FULL TEXT OF THE REQUEST FOR APPLICATIONS (RFA) CONTAINS ESSENTIAL INFORMATION AND MUST BE REQUESTED BEFORE AN APPLICATION IS PREPARED - SEE INQUIRIES SECTION.

PURPOSE

The Division of Kidney, Urologic and Hematologic Diseases (DKUHD) invites cooperative agreement applications for investigators to design and implement a pilot study trial to assess the feasibility of conducting a full-scale multicenter randomized clinical trial to evaluate the effects of drug treatment on the progression of and symptoms due to benign prostatic hyperplasia (BPH).

The assistance mechanism used to support the study is the cooperative agreement, which is similar to the traditional NIH research grant. Applications are requested for Clinical Centers, a the Data Coordinating Center, and/or the Diagnostic Center (DC). A center selected as a Clinical Center also may serve as the Data Coordinating Center and/or the Diagnostic Center, however, separate applications will be required for each of these study components.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications, Treatment of Benign Prostatic Hyperplasia: Pilot Study, is related to the priority area of diabetes and chronic disabling diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock Number 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock Number 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Domestic universities, medical colleges, hospitals, and other public and private research institutions, including State and local government units, are eligible. Applications from minority investigators and women are especially encouraged.

An institution may apply to be a Clinical Center, the Data Coordinating Center, and/or the Diagnostic Center. However, a specific plan is required within the applications for how the independent operation (i.e., confidentiality of study-wide data) of each unit will be maintained. Collaboration among institutions to carry out the study is encouraged. Institutions wishing to collaborate and function as a single Clinical Center are required to submit one application.

MECHANISM OF SUPPORT

The administrative and funding mechanism will be the cooperative agreement (U01). Funding is expected to begin in September 1992; total support for the project will be for 30 months.

FUNDS AVAILABLE

It is anticipated that six awards (four Clinical Centers, one Data Coordinating Center, and one Diagnostic Center) will be made under this RFA for a total of approximately \$1,600,000 (including direct and indirect costs) during the first year. The funding levels for the Clinical Centers will be approximately \$200,000 in

total costs per center annually; the Data Coordinating Center will be funded at approximately \$300,000 in total costs per year, and the Diagnostic Center will be funded at approximately \$500,000 in total costs per year.

RESEARCH OBJECTIVES

The primary purpose of this RFA is to initiate a collaborative pilot study of drug therapy for BPH to reduce occurrence of symptoms and slow or halt disease progression. The pilot study will test the feasibility of conducting a full-scale randomized clinical trial in an adequately sized patient population.

Scope of the Activity: It is expected that the pilot study will take place in four Clinical Centers over a period of 30 months. Each Clinical Center will randomize a minimum of 25 study participants over a 12-month period of recruitment. The study will be in three phases: (I) a 9-month period of collaborative protocol development; (II) 12 months of patient recruitment and follow-up; and (III) 9 months of close-out of the pilot phase, data analysis, and reporting of results.

Each applicant is expected to propose the study design believed to be most appropriate for this project. Applicants must provide a detailed justification for whatever strategy is proposed for subject selection, an estimate of the number of subjects in the source population and in the final examination sample, and an estimate of the necessary time and effort needed for recruitment. Applicants also must address criteria and outcome measures for the pilot study objectives by which success of this phase of the program will be judged for extension into the full-scale study.

Study Phases: The entire pilot study will consist of three sequential phases as indicated above. It is anticipated that the long-range operational plan of the entire study, including the pilot study, will consist of five sequential phases as follows:

Phase I Development of Pilot Study Protocol (9 months)

Phase II Conduct of Pilot Study (12 months)

Phase III Close-out and Analysis of Pilot Study Data (9 months)

Phase IV Conduct of Full-Scale Cooperative Clinical Trial (72 months)

Phase V Data Analysis and Reporting of Results of the Full-Scale Study (12 months)

Based upon meeting the goals and objectives of the pilot study and a recommendation from the External Advisory Committee, the NIDDK will issue a separate RFA for the full-scale study in order to provide a sufficient recruitment base.

Budget Preparation by Study Phase: Each applicant for a Clinical Center, the Data Coordinating Center, and the Diagnostic Center must submit adequately justified budgets for the entire anticipated project period of 30 months. The budgets for each budget period of the study must be clearly delineated. Detailed budget preparation information is provided in the RFA.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of minorities in study populations. If minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked, but not required, to submit a letter of intent. This letter is to include the name, telephone number and mailing address of the Principal Investigator, the names of other key personnel, the name of the applicant institution, and the number and title of this RFA. Letters of intent to apply to this RFA, are to be received no later than June 2, 1992 and are to be addressed to:

Dr. Robert D. Hammond
Chief, Review Branch, Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 605
Bethesda, MD 20892
Telephone: (301) 496-7083
FAX: (301) 402-1277

Technical Assistance Seminar

A special technical assistance seminar will be offered to assist potential applicants who have limited experience with the NIH application process or who wish further clarification of the cooperative agreement application process. The NIH cannot support individuals who wish to attend the conference but it will be open to any individual who wishes to attend. The meeting will be held approximately May 22 at the National Institutes of Health, Bethesda, Maryland. The exact time and location of the seminar may be obtained by contacting the Urology Program Director listed in INQUIRIES.

APPLICATION PROCEDURES

Submit applications on form PHS 398 (rev. 9/91). Copies of this form are available in the applicant institution's office of sponsored research and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, Maryland 20892, Telephone: (301) 496-7441.

Applications must be received by June 17, 1992. An application not received by this date will be ineligible and returned to the applicant.

REVIEW CONSIDERATIONS

Upon receipt, the Division of Research Grants will review the application for completeness. Applications will be reviewed by NIDDK staff for responsiveness to the objectives of this RFA. If an application is judged unresponsive, the applicant will be contacted and given the opportunity to withdraw the application, or have it considered for the unsolicited NIH grant program.

The evaluation of applications for Clinical Centers, the Data Coordinating Center, and the Diagnostic Center will be based primarily on the scientific merit of the proposed study. Specific criteria for review of each type of application are given in the RFA.

INQUIRIES

Potential applicants are advised to obtain a copy of this RFA from the Urology Program Director listed below. Inquiries regarding this announcement should be addressed to the following:

Leroy M. Nyberg, Jr., Ph.D., M.D.
Director, Urology Program
National Institute of Diabetes and Digestive and Kidney Diseases
5333 Westbard Avenue
Westwood Building, Room 3A05
Bethesda, MD 20892
Telephone: (301) 496-7133
FAX: (301) 402-0223

AUTHORITY AND REGULATIONS

These programs are described in the catalog of Federal Domestic Assistance No. 93.849, Kidney, Urologic and Hematologic Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-4110, as amended: 42 USC 241) and administered under PHS Grants Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

PATOPHYSIOLOGY OF ENDOMETRIOSIS AND LEIOMYOMATA UTERI

NIH GUIDE, Volume 21, Number 16, May 1, 1992

RFA AVAILABLE: HD-93-04

P.T. 34; K.W. 0765035, 0710110, 0710115, 0760020, 0775020

National Institute of Child Health and Human Development
Office of Research on Women's Health

Application Receipt Date: July 24, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The National Institute of Child Health and Human Development (NICHD) and the Office of Research on Women's Health (ORWH) invite research grant applications for support of investigations into the biology and pathophysiology of endometriosis and leiomyomata uteri ("myoma"). Directives from the 102nd U.S. Congress have urged the NIH to address research efforts toward several diseases and conditions related to women's health including endometriosis and myoma.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Pathophysiology of Endometriosis and Leiomyomata Uteri, is related to the priority area of family planning. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private. Minority individuals, persons with disabilities, and women are encouraged to apply.

MECHANISM OF SUPPORT

This RFA will use the NIH individual research grant (R01) mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed five years.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

FUNDS AVAILABLE

It is expected that up to five applications will be funded, within the total cost limit of \$1,000,000 available for the first year. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NICHD and the ORWH, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

Areas that will be considered responsive to this RFA include, but are not limited to:

- o Mechanisms by which endometriotic lesions arise and proliferate;
- o Elucidation of effectors of myoma growth regulation, specific to leiomyomata uteri rather than tumorigenesis in general;
- o New approaches to intervention based on established responses of endometriosis or myoma cells to hormonal, immune, or growth factors;
- o Use of improved animal and cell culture model systems for the study of endometriosis or myoma relating to the above;
- o Elucidation of factors contributing to reduced incidence of clinical pregnancy in women with endometriosis or myoma.

While applicants are encouraged to include a clinical research component, it is not the intent of this RFA to support clinical trials. Applications proposing clinical trials should not be submitted in response to this RFA.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. For the purpose of this RFA, investigations are limited to disorders occurring only in women. If minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/496-7441. The receipt date for applications submitted in response to this RFA is July 24, 1992. Late applications will be returned to the applicant.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. If the application is not responsive to the RFA, it will be returned to the applicant. Responsive applications may be triaged by a peer review group to determine relative competitiveness. The NIH will withdraw from further consideration those applications judged to be non-competitive for award and notify the applicant Principal Investigator and institutional official. Those applications judged to be competitive will undergo further evaluation for scientific merit by an initial review group convened by the Division of Research Grants. Review criteria for RFAs are generally the same as those for unsolicited research grant applications. The second level of review will be provided by the National Advisory Child Health and Human Development (NACHHD) Council.

AWARD CRITERIA

The anticipated date of award is September 30, 1992. Funding decisions will be based on IRG and NACHHD Council recommendations, program relevance, and availability of funds.

INQUIRIES

Direct requests for the RFA and inquiries regarding programmatic issues to:

Donna L. Vogel, M.D., Ph.D
Reproductive Sciences Branch
Center for Population Research
National Institute of Child Health and Human Development

Executive Plaza North, Room 603
Bethesda, MD 20892
Telephone: (301) 496-6515
FAX: (301) 496-0962

Direct inquiries regarding fiscal matters to:

Melinda Nelson
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 505
Bethesda, MD 20892
Telephone: (301) 496-5481

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.864, Population Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

COOPERATIVE COMMUNITY-BASED PERINATAL STUDIES AND INTERVENTIONS IN MINORITY POPULATIONS

NIH GUIDE, Volume 21, Number 16, May 1, 1992

RFA AVAILABLE: HD/NR/OMP-92-07

P.T. 34, FF; K.W. 0775025, 0403004, 0745035, 0411005, 0414014

National Institute of Child Health and Human Development
National Center for Nursing Research
Office of Minority Programs

Letter of Intent Receipt Date: May 25, 1992
Application Receipt Date: July 22, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The National Institute of Child Health and Human Development (NICHD), in cooperation with the National Center for Nursing Research (NCNR) and the Office of Minority Programs (OMP), invites applications for cooperative agreements to participate in planning and conducting research that addresses the problem of the unacceptably high infant mortality rate among minority populations in this country. Specifically, the National Institutes of Health (NIH) will assist the community (using the cooperative agreement mechanism) in establishing a model population-based perinatal epidemiology and clinical research effort to conduct research aimed at increasing the understanding of the determinants of the high infant mortality rate in Washington DC and its related outcomes, such as low birth weight, intrauterine growth retardation, and preterm delivery. It is expected that research will include areas that lend themselves to intervention and may address different aspects of the overall infant mortality problem. It may include outreach and provisions of appropriate and enriched prenatal care for high risk pregnant women; interventions to improve health behavior during pregnancy, such as smoking, drinking, and drug abuse; and the testing of methods to increase early participation in prenatal care for population groups that traditionally receive no or late prenatal care. The results of this model program are expected to be applicable to other cities with large minority populations.

Applications for a cooperative agreement with a Data Center for the network are also invited. This center will manage data from interventions and surveys at the funded sites. The Data Center should be functionally independent of all research sites, although it could be physically located at one of them.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Cooperative Community-Based Perinatal Studies and Interventions in Minority Populations, is related to the priority areas of infant mortality, fetal deaths, low birth weight, severe complications of pregnancy, and prenatal care. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by for-profit and non-profit, public and private, organizations **WITHIN THE DISTRICT OF COLUMBIA**, (although the Data Center may be located elsewhere), such as medical schools, universities, colleges, hospitals, laboratories, community-based organizations, and units of local government. For-profit organizations interested in applying under this RFA should note that no profit or fees may be requested under this kind of assistance award. In addition, since there are no-cost principles applicable to for-profit organizations receiving financial assistance awards, those set forth in Federal Acquisition Regulations in 48 CFR Part 31.2 will generally be used.

Institutions may submit singly or in partnerships with two or more organizations or groups. Both community and research capabilities must be represented regardless of which organization is submitting as the applicant entity.

MECHANISM OF SUPPORT

The funding mechanism to be used to assist the community in undertaking this coordinated program of community-based clinical trials will be a cooperative agreement mechanism, the Research Demonstration Cooperative Agreement (U18). This grant mechanism provides "support for testing, by means of a research design, the effectiveness of the transfer and application of techniques or interventions derived from a research base for the control of diseases or disorders, or for the promotion of health. The project should be capable of making conclusions which are generally applicable to other sites."

The major difference between a cooperative agreement and a research project grant is that there will be substantial programmatic involvement of the NICHD Project Coordinator above and beyond the levels required for traditional program management of grants. Specifically, an NICHD staff member will cooperate with Principal Investigators as a partner in the funded projects and serve as the Project Coordinator. All parties will agree to accept the participatory and cooperative nature of the group process. Due to the cosponsorship by the NCNR, a project coordinator from that Center will also participate, as will the Director of the OMP or his designee.

For details about the primary rights and responsibilities of the awardees, and the nature of NICHD, NCNR, and OMP staff participation in this cooperative effort, applicants should contact the Project Coordinator(s) and request a copy of the RFA, in which all the terms and conditions of the grant are described.

This RFA is a one-time solicitation. However, if it becomes apparent that there is a continuing program need, the NICHD may reannounce this RFA at the end of the current project period. The total project period for applications submitted in response to the present RFA may be five years. The anticipated award date will be September 30, 1992.

FUNDS AVAILABLE

The estimated funds available for the first year of support for the entire program, which will consist primarily of planning and protocol development, are \$500,000 total costs. It is estimated that Data Center costs for year one could be up to \$38,000 total costs. Approximately \$462,000 total cost would be available or an average of \$57,750 per research award. Supplemental funds will be added in future years to cover costs of the protocols. It is estimated that Data Center costs could be up to \$345,000 for year 02. Approximately \$4,655 million total cost would be available or an average of \$581,875 total cost per research award. It is expected that seven to nine awards will be made, including the Data Center. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the participating organizational entities, the award of grants pursuant to this RFA is also contingent on the availability of funds for this purpose.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 25, 1992, a letter of intent that includes a descriptive title of the proposed research, the name, address and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application will be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It also allows staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Heinz W. Berendes, M.D., M.H.S.
Director, Division of Epidemiology, Statistics and Prevention Research
National Institute of Child Health and Human Development
6130 Executive Boulevard
Executive Plaza North, Room 640
Bethesda, MD 20892
Telephone: (301) 496-5064

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 596-7441. Applications must be received by July 22, 1992.

REVIEW CONSIDERATIONS

Applications will be received by the Division of Research grants and reviewed for completeness. Incomplete applications will be returned to the applicant without further consideration. NICHD, NCNR, and OMP staff will review for responsiveness. Applications not responsive to the RFA will also be returned. Complete and responsive applications will be evaluated for scientific/technical merit by a review group specifically convened by NICHD for this purpose. Applications may be subjected to triage by an NICHD peer review group to determine scientific merit relative to other applications received in response to this RFA. The second level of review will be provided by the Advisory Councils of the participating awarding components.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged, and the opportunity to clarify any issues or questions from potential applicants is welcome. Direct requests for the RFA and inquiries regarding programmatic issues to Dr. Heinz W. Berendes at the address under LETTER OF INTENT.

Inquiries regarding fiscal matters may be directed to:

E. Douglas Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 505
Bethesda, MD 20892
Telephone: (301) 496-1303
FAX: (301) 402-0915

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.865, Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC241), and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to review under the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

RESEARCH ON THE HOMELESS WITH ALCOHOL PROBLEMS

NIH GUIDE, Volume 21, Number 16, May 1, 1992

PA AVAILABLE: PA-92-70

P.T. 34; K.W. 0404003, 0745027, 0415001

National Institute on Alcohol Abuse and Alcoholism

PURPOSE

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) invites researchers to submit research grant applications dealing with the identification, treatment, and rehabilitation of homeless people with alcohol problems and the prevention of alcohol abuse and alcoholism among homeless people who are not alcoholics. This program announcement is a revised version of an earlier announcement with the same title issued in March 1989.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. This program announcement, Research on the Homeless with Alcohol Problems, is related to the priority area of decreasing morbidity and mortality associated with alcohol abuse and alcoholism. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone: 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications for research grants may be made by public and private non-profit and for-profit organizations, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

MECHANISMS OF SUPPORT

Research support may be requested through applications for an individual research grant (R01), small grant (R03), and First Independent Research Support and Transition (FIRST) Award (R29). Special announcements for the FIRST Award program (R29) and the small grant program (R03) are available from the National Clearinghouse for Alcohol and Drug Information (address below).

FUNDS AVAILABLE

No specific funds are being allocated by NIAAA for this program. Applications received in response to this announcement will compete with others submitted to NIAAA for funding. The amount of funding available will depend on appropriated funds, quality of research proposals, and program priorities at the time of the award. In FY 1991, four grants relating to this program area, including both new and continuation grants, were funded for \$1.25 million.

RESEARCH OBJECTIVES

The purpose of this program announcement is to encourage investigator interest in the area of the homeless population with alcohol problems, including those at imminent risk of becoming homeless. Investigators are also encouraged to study the role of alcohol in conjunction with other drug abuse and mental health problems in the

homeless. Research is sought on the following topics:

- o assessing the impact of existing treatment service models and specific interventions that are effective in reducing alcohol problems among the homeless;
- o developing new techniques and service delivery models for effectively treating alcohol problems among the homeless;
- o identifying barriers to community treatment services and determining means to improve access to care;
- o evaluating current service systems in terms of relative effectiveness in reducing alcohol problems among the homeless;
- o developing and assessing strategies to prevent alcohol abuse/alcoholism among the non-alcoholic homeless and those at imminent risk of becoming homeless;
- o identifying "routes to treatment" taken by the alcohol troubled homeless. Specifically, what events tend to result in the homeless with alcohol-related problems receiving medical, psychological, or social assistance, and how effectively does the human services network respond in terms of addressing alcohol problems if they are present;
- o developing methods to follow this population effectively and to obtain valid information to determine long-term effectiveness of alcoholism treatment;
- o performing cost analyses regarding alcoholism treatment among the homeless; and
- o surveying the public, the cognizant providers, and the homeless population itself regarding alcoholism treatment service needs, attitudes toward treatment, and beliefs about effectiveness of alcoholism treatment services for the homeless.

Where applicable, outcome measures for such studies should include drinking measures as well as economic and social measures.

SPECIAL INSTRUCTIONS FOR INCLUSION OF MINORITIES AND WOMEN AS SUBJECTS IN RESEARCH

For projects involving clinical research, NIH and ADAMHA require applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included or adequately represented in the study populations for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

All applications for clinical research submitted to ADAMHA are required to address these policies. ADAMHA funding components will not award grants that do not comply with these policies.

APPLICATION PROCEDURES

Applicants are to use the grant application form PHS 398 (rev. 9/91). The number and title of this announcement, "Research on the Homeless with Alcohol Problems PA-92-70," must be typed in item number 2a on the face page of the PHS 398 application form.

Application kits containing the necessary forms and instructions (PHS 398) may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following office may be contacted for the necessary application material:

National Clearinghouse for Alcohol and Drug Information
P.O. Box 2345
Rockville, MD 20852
Telephone: (301) 468-2600 or 1-800-729-6686

The signed original and five permanent, legible copies of the completed application must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary PHS grant programs. Applications received under this announcement will be assigned to an Initial Review Group (IRG) in accordance with established PHS Referral Guidelines. The IRGs, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit. Notification of the review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by an appropriate National Advisory Council. Only applications recommended by a Council may be considered for funding.

AWARD CRITERIA

Applications will be considered for funding on the basis of overall scientific and technical merit of the research as determined by peer review, program needs and balance, and the availability of funds.

INQUIRIES

Potential applicants are encouraged to seek preapplication consultation and may contact the individual listed below for consultation in preparing an application under this announcement. Direct inquiries to:

Fulton Caldwell, Ph.D.
Treatment Research Branch
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
5600 Fishers Lane, Room 14C-20
Rockville, MD 20857
Telephone: (301) 443-0796

Inquiries relating to fiscal matters must be directed to:

Elsie Fleming
Grants Management Branch
Office of Planning and Resource Management
National Institute on Alcohol Abuse and Alcoholism
Parklawn Building, Room 16-86
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4703

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.273. Awards are made under the authority of Sections 301 and 510 of the Public Health Service Act, as amended (42 USC 241 and 290bb), and under the authority of Section 1992 of the PHS Act (42 USC 300X-9a). Federal regulations at 42 CFR Part 52, "Grants for Research Projects," and Title 45 CFR Parts 74 and 92, generic requirements concerning the administration of grants, are applicable to these awards. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

HEALTH SERVICES RESEARCH ON RURAL HEALTH

NIH GUIDE, Volume 21, Number 16, May 1, 1992

PA NUMBER: PA-92-71

P.T. 34; K.W. 0730050, 0403004, 0745027, 0745035

Agency for Health Care Policy and Research

PURPOSE

The purpose of this program announcement (PA) is to stimulate the development of new research in the areas of delivery, organization, and financing of rural health services. The Agency for Health Care Policy and Research (AHCPR) invites research applications that address important research questions in rural health.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a statement of national health goals in 21 priority areas, to be met by the year 2000. Many of the issues addressed within the broad range of topics covered by this PA, Health Services Research on Rural Health, are related to these priority areas. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign non-profit organizations, public and private, including universities, clinics, units of State and local governments, non-profit firms, and non-profit foundations. Applications from minority and women investigators are encouraged.

MECHANISM OF SUPPORT

This PA is intended for the traditional research grant program (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. It is anticipated that projects will vary from one to three years in length. Project lengths may be up to five years in rare cases due to the complexity or breadth of the subject area.

RESEARCH OBJECTIVES

Background

AHCPR conducts and supports research, demonstrations, and evaluations of the quality, appropriateness, and effectiveness of health care services and systems for the delivery of such services. This announcement focuses on these issues in respect to rural areas and underserved populations residing in rural areas.

New rural health problems have developed in recent years and some rural health problems have worsened. Newly emerging rural health issues such as AIDS, State and Federal policy changes, and increased emphasis on managed care have been woven into the research agenda with longstanding issues, such as health professionals, emergency services, and care of indigent persons. In addition, there is increasing interest in learning whether or not differences in care delivered to rural residents, compared to urban counterparts, are associated with different health outcomes.

Objectives

The following topic areas and questions are illustrative of relevant research needed to improve the scientific base for informed rural health policy recommendations. The issues raised in the different sections are often interdependent; those raised in a particular section may be applicable to topics in other sections as well.

Access

A key issue facing policy makers is ensuring access to care in rural areas where small hospitals have closed, other health facilities are having financial difficulty, availability of primary health care practitioners is declining, and mid-level practitioners are leaving practice or leaving the rural area.

- o What are the dimensions and characteristics of access problems in rural areas? What services and what resources are necessary to meet a minimal level of need? What discrete services are unavailable and how should they be provided?
- o What impact has the medical liability situation had on the practice patterns of providers in rural areas and, in particular, on availability of care for pregnant women?

Health Professionals

There are many factors that affect the supply of physicians, nurses, and other health professionals in rural communities, such as: the demand for services, the availability of continuing education, professional concerns with quality assurance, lifestyle preferences, and availability of support services. Unanswered questions include:

- o What factors of geography, community, health facilities, and practice affect the mix and availability of medical personnel in rural practice?
- o What techniques of recruitment and retention of health care professionals have been used successfully?

Emergency Care Delivery Systems

One quarter of Americans live in rural areas, which occupy four-fifths of the nation's land areas. Residents of these areas face special problems in receiving emergency care. Research questions regarding rural emergency care are:

- o How can emergency transportation and communication problems be improved in rural areas, especially those with poor roads or without 911 services or similar emergency numbers?
- o What are the appropriate criteria and standards that govern effective stabilization, triage, and referral to regional trauma and medical centers; what are the barriers to regionalization, and what can be done to further promote adoption of coordinated emergency care programs?

Rural Hospital and Hospital-based Delivery Systems

Rural hospitals form a vital connection in a community's health care system and economy. Growing financial stress and decline and closure of rural hospitals raise concerns about access to health care. During the 1980s, Congress enacted a number of programs aimed at strengthening rural hospitals and health care services to improve access. Suggested research questions are:

- o What are the effects of Federal initiatives on maintaining access to rural health services, hospital survival, and community social and economic well-being?
- o Are there differences in quality of care, case mix, and uncompensated care between rural hospitals that are members of hospital chains and those that are not?

Alternative Delivery Systems and Managed Care

The term "managed care" includes a variety of administrative structures that integrate the financing and delivery of health care in an effort to improve the cost-effectiveness of health care. Managed care organizations have emerged in response to increasing pressures to contain costs without sacrificing quality, and may enhance the coordination and quality of care. Little is known about the effectiveness of managed care organizations in rural areas. Suggested research questions include:

- o What has been the experience of managed care organizations in rural areas with respect to market penetration and effects on access to care?
- o How do managed care organizations in rural areas compare to those in urban and suburban settings with respect to costs, quality of care, and patterns of utilization?

Provision of Primary Health Care

Limited research exists on primary care practice and its quality and variation in rural areas. Insufficient attention has been paid to assuring the continued viability of primary care and to documenting the effects of changes in funding and support of primary care services in rural areas. Research questions on primary care include:

- o What is the extent of medical practice variation within and between rural areas and between urban and rural areas? Are there differences in the use of specific services and in health outcomes for particular medical problems treated?
- o What are the most effective alternative models for providing primary care that are responsive to the specific health needs of local rural communities?

Health Promotion and Disease Prevention

Prevention objectives identified in "Healthy People 2000" can be achieved by removing barriers that impede access to and use of clinical preventive services. Research issues for health promotion and disease prevention in rural populations are:

- o What factors unique to rural areas do health promotion/disease prevention programs and strategies need to consider in order to be successful in changing provider and/or consumer behavior with respect to health promotion/disease prevention recommendations?
- o How can rural health care providers, community leaders, and voluntary agencies develop and implement cost-effective health promotion and disease prevention programs?

Technology

Significant barriers to technology diffusion to rural areas exist. The cost of financing a new technology when high volume use is not anticipated is often a limiting factor. Limitations in access to technology often raise questions about quality of care. Some questions are:

- o How can technology be used to improve care in isolated rural areas? In what areas of care is technology most likely to make a difference in access, cost, or quality of care rendered?
- o What technology could enhance communication and knowledge transfer between specialists in urban health care facilities and rural practitioners, and facilitate provision of state-of-the-art care by rural practitioners?

STUDY POPULATIONS

Research is encouraged on the delivery of services to people with AIDS, the homeless, the elderly, rural poor, mothers, children, and adolescents, and rural/ethnic minority populations. Examples of research needed are:

- o Studies of health care utilization, health status and access to coordinated community services for special populations in rural areas, and basic demographic studies of their social characteristics.
- o Studies of variations in informal caregiving among the rural elderly by racial and ethnic characteristics.

SPECIAL INSTRUCTIONS TO APPLICANTS CONCERNING INCLUSION OF WOMEN AND MINORITIES IN RESEARCH STUDY POPULATIONS

The AHCPR requires all applicants for research grants to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study. Special emphasis must be placed on the need to include minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in research, a clear and compelling rationale should be provided. AHCPR will not award grants for applications which do not comply. If the required information is not contained in the application, the application will be returned without review.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, AHCPR recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans, Asian/Pacific Islanders, Blacks, Hispanics). Where appropriate, the applicant must provide the rationale for studies on single minority population groups.

This policy applies to all biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for research submitted to AHCPR are required to address these policies. AHCPR will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91), and will be accepted at the standard application deadlines as indicated in the application kit. State and local governments may use Form PHS 5161 and submit an original and two copies of the application.

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, MD 20892, telephone 301/496-7441. They may also be obtained from the Office of Scientific Review, Agency for Health Care Policy and Research, Suite 602, 2101 East Jefferson Street, Rockville, MD 20852, telephone 301-227-8449. The title and number of the announcement must be typed in Section 2a on the face page of the application.

The completed original application and five legible copies (two copies when using the PHS 5161) must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

The first due date is October 1, 1992. Thereafter, the due dates for applications are February 1, June 1, and October 1. However, an application received after the deadline may be acceptable if it carries a legible proof-of-mailing date assigned by the carrier and the proof-of-mailing date is not later than one week prior to the deadline date. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following work day. The receipt date will be waived only in extenuating circumstances. To request such a waiver, an explanatory letter must be included with the application. No waiver will be granted prior to receipt of the application.

REVIEW CONSIDERATIONS

The review criteria for these applications are: significance and originality from a scientific and technical viewpoint; adequacy of the method to carry out the project; availability of data or the proposed plan to collect data required for the project; qualifications and experience of the Principal Investigator and proposed staff; adequacy of the plan for organizing and carrying out the project; reasonableness of the proposed budget; and adequacy of the facilities and resources available to the applicant.

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary PHS grant programs. Applications received under this announcement will be assigned to an Initial Review Group (IRG) in accordance with established PHS Referral Guidelines. The IRGs, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit. Notification of the review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by an appropriate National Advisory Council. Only applications recommended by a council may be considered for funding.

AWARD CRITERIA

Applications will compete for available funds with all other applications. The following will be considered in making funding decisions: Quality of the proposed project as determined by peer review, availability of funds, and program balance among research areas of the announcement.

INQUIRIES

Those considering an application in response to this PA are strongly encouraged to discuss the project with the AHCPR program administrators before formal submission. The AHCPR Welcomes the opportunity to clarify any issues or questions from potential applicants. A Grant Announcement discussing research issues in this PA will be available from the AHCPR Publications Clearinghouse, PO Box 8547, Silver Spring, MD 20907, (1-800-358-9295) by June 15, 1992.

Direct inquiries regarding programmatic issues to:

Paul Nutting, M.D., M.S.P.H.
Director, Division of Primary Care
Center for General Health Services Extramural Research
Agency for Health Care Policy and Research
Executive Office Center, Suite 502
2101 East Jefferson Street
Rockville, MD 20852-4908
Telephone: (301) 227-8357
FAX: (301) 227-8155

Direct inquiries regarding fiscal matters to:

Ralph Sloat
Grants Management Officer
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 601
Rockville, MD 20852-4908
Telephone: (301) 227-8447

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.180 and 93.226. Awards are made under authorization of the Public Health Service Act, Title IX, as amended (Public Law 101-239) and administered under PHS grants policies and Federal Regulations 42 CFR 67, Subpart A and 45 CFR Part 74, (45 CFR Part 92 for State and local governments). This program is not subject to the intergovernmental review requirements of Executive Order 12372.

MINORITY INSTITUTIONAL RESEARCH TRAINING PROGRAM

NIH GUIDE, Volume 21, Number 16, May 1, 1992

PA NUMBER: PA-92-72

P.T. 44, FF; K.W. 0720005, 0715040, 0715165, 0785070

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: July 1, 1992

Application Receipt Date: August 24, 1992

PURPOSE

The National Heart, Lung, and Blood Institute (NHLBI) announces a program to support full time research training for investigative careers at minority schools in areas related to cardiovascular, pulmonary, and hematologic diseases.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Minority Institutional Research Training, is related to the priority area of heart disease and stroke. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Grants in this program will be made to minority institutions, each of which will collaborate with a research center that has well-established cardiovascular, pulmonary, or hematologic research and research training programs. The applicant institution must be a domestic medical or non-medical college, university or equivalent school in which students of underrepresented minority groups, including Blacks, Hispanics, American Indians, and Asian and Pacific Islanders, comprise a majority or a significant proportion of school enrollment. The program director at the minority school will be responsible for the selection and appointment of trainees and the overall direction of the training program.

The collaborating research center should be a medical school or comparable institution that has strong, well-established cardiovascular, pulmonary, or hematologic research and research training programs. Cooperation between institutions is needed to provide each trainee with a mentor who is recognized as an accomplished investigator in cardiovascular, pulmonary, or hematologic research and who will assist the advisor at the minority institution in the trainee's development and research plan.

Each trainee will be placed with a mentor who is an accomplished investigator at the cooperating research center and who will assist the advisor at the minority institution in the trainee's development and research plan. Trainees must be training at the post-baccalaureate level in a relevant biomedical or behavioral science and have made a strong commitment to completing a doctoral degree, be enrolled in a minority health professional school, and have a doctoral degree or equivalent in a biomedical or behavioral science.

MECHANISM OF SUPPORT

The mechanism of support is the Institutional National Research Service Award (T32) research training grant. Institutions may request up to five years of support. Training programs may support predoctoral students, postdoctoral trainees, and short-term trainees in health professional schools. Stipend levels for predoctoral and short-term trainees are \$8,800 per year and stipend levels for postdoctoral trainees range from \$18,600 to \$32,300 per year. Stipends may be supplemented from non-Federal sources. Training related expenses, tuition and fees, and travel expenses may also be requested for trainees, although the levels may vary depending on the type of training to be supported. The trainees may be appointed for 9-12 months (for short-term trainees, the period of appointment may be of 2 to 3 months duration) at any time during the course of the budget period after he/she has been accepted as a full-time student. A strong interest in a cardiovascular, pulmonary, or hematologic research career must be evident. Indirect costs will be awarded based on eight percent of total direct costs with no exclusions from the base for training-related expenses.

RESEARCH OBJECTIVES

The Minority Institutional Research Training Program is designed to offer research training grant awards in cardiovascular, pulmonary, and hematologic research to minority schools to enable qualified graduate students, health professional students, and postdoctoral students to participate in research programs. It is expected to attract students in the developmental stages, increase awareness of these diseases, and to acquaint them with career opportunities in research.

The Minority Institutional Research Training Program is intended to:

- o Train graduate students, health professional students, and postdoctoral students at minority schools that have the potential to develop a meritorious program in cardiovascular, pulmonary, or hematologic* research for research careers in areas relevant to these diseases.
- o Stimulate cardiovascular, pulmonary, and hematologic diseases and hematologic resources research, prevention, control, and education by offering minority school graduate students, health professional students, and postdoctoral students the opportunity to enhance their research capabilities in these areas.

* Within NHLBI, the term "hematologic" covers research on thrombosis and hemostasis, immunohematology, blood cell disorders, sickle cell disease, blood resources, including blood component and derivative therapy, blood substitutes and blood resource management, aspects of AIDS products in AIDS prevention and treatment, and AIDS-related bone marrow and hematologic disorders. Other Institutes of the NIH are responsible for research on disorders of white cells, including the leukemias, and other blood malignancies, and basic immunology related to the lymphoid system. Therefore the NHLBI does not provide support for such studies.

LETTER OF INTENT

Each prospective applicant is requested to forward a letter of intent that includes a descriptive title, the name and address of the Program Director, the name and location of the institution to serve as the research center, names of key investigators, and any other participating institutions. Such letters are requested for the purpose of obtaining an indication of the number and scope of the applications to be reviewed. A letter of intent is not binding, is not a requirement of submission, and does not enter into the review of the application. The letter of intent is requested by July 1, 1992, and is to be addressed to:

Scientific Review Administrator
Research Training Review Committee
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 550
Bethesda, MD 20892

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441. The title and number of the announcement must be typed in section 2a on the face page of the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applications must be received on or before August 24, 1992.

REVIEW PROCEDURES

All applications responding to this announcement will be reviewed for scientific and technical merit by the Research Training Review Committee of the Division of Extramural Affairs, NHLBI, followed by a second level review by the National Heart, Lung, and Blood Advisory Council.

AWARD CRITERIA

Applications will compete for available funds with other approved applications assigned to the National Heart, Lung, and Blood Institute. The following will be considered in making funding decisions:

- o Scientific and technical merit of the application as determined by peer review
- o Availability of funds
- o Program balance among the research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. Guidelines for this program may be obtained from any of the following:

John Fakunding, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 3C04
Bethesda, MD 20892
Telephone: (301) 496-1724

Helena Mishoe, Ph.D.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building, Room 504
Bethesda, MD 20892
Telephone: (301) 496-6931

Mary Reilly, M.S.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 640A
Bethesda, MD 20892
Telephone: (301) 496-7668

For fiscal and administrative matters, please contact:

Grants Operations Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A15C
Bethesda, MD 20892
Telephone: (301) 496-7255

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.837, 93.838, and 93.839. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SHORT-TERM TRAINING FOR MINORITY STUDENTS PROGRAM

NIH GUIDE, Volume 21, Number 16, May 1, 1992

PA NUMBER: PA-92-73

P.T. 44, FF; K.W. 0720005, 0715040, 0715165, 0785070

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: July 1, 1992
Application Receipt Date: August 24, 1992

PURPOSE

The National Heart, Lung, and Blood Institute (NHLBI) announces the third competition for the Short-Term Training for Minority Students Program. The purpose of this National Research Service Award (NRSA) short-term training program for minority students is to encourage institutions to provide minority undergraduate students, graduate students, and students in health professional schools exposure to opportunities inherent in research careers in areas relevant to cardiovascular, pulmonary, and hematologic diseases.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Short-Term Training for Minority Students, is related to the priority area of heart disease and stroke. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents,

ELIGIBILITY REQUIREMENTS

Grants in this program will be made to domestic institutions and organizations, including minority institutions, engaged in health related research in areas related to heart, lung and blood disorders. These grants will support short-term research training experiences of two to three months duration for minority undergraduate students, minority students in health professional schools, and minority graduate students. Trainees appointed to the program need not be from the grantee institution, but may include a number of minority students from other institutions, schools, colleges and universities. Special attention must be given to the recruitment of individuals from minority groups that are underrepresented nationally in the biomedical and behavioral sciences, i.e., Blacks, Hispanics, Native Americans, Alaskan Americans, and Pacific Islanders.

MECHANISM OF SUPPORT

The mechanism of support is the Institutional National Research Service Award (T32). Institutions may request up to 5 years of support for short-term training programs for at least 4 and not more than 24 trainees per year. The stipend level for trainees is \$733 per month. Stipends may be supplemented from non-Federal funds. Training-related expenses up to \$125 per month per trainee may be requested. In addition, up to \$500 per trainee may be requested to cover domestic travel to and from the training site and up to \$250 per month per trainee may be requested to cover the cost of housing at the training site. Trainee tuition and fees, where necessary to the research training, must be covered by the Training Related Expenses. Indirect costs will be awarded based on eight percent of total direct costs with no exclusions from the base for training related expenses.

RESEARCH OBJECTIVES

The Short-Term Training for Minority Students Program is intended to:

- o Provide minority undergraduate students, graduate students, and students in health professional schools exposure to opportunities inherent in research careers in areas relevant to cardiovascular, pulmonary, and hematologic* diseases;
- o Attract highly qualified minority students into biomedical and behavioral research careers in the areas of heart, lung, and blood disorders; and
- o Bolster the already short supply of minority investigators and attract highly qualified minority students into biomedical and behavioral research careers.

* For the purposes of this award, the term "hematologic" covers research on thrombosis and hemostasis, immunohematology, blood cell disorders, sickle cell disease, blood resources, including blood component and derivative therapy, blood substitutes and blood resource management, aspects of AIDS products in AIDS prevention and treatment, AIDS-related bone marrow and hematologic disorders, and the lymphocirculatory system.

LETTER OF INTENT

Each prospective applicant is requested to forward a letter of intent, that includes a descriptive title, the name and address of the Program Director, and any other participating institutions. Such letters are requested for the purposes of obtaining an indication of the number and scope of the applications to be reviewed. A letter of intent is not binding, is not a requirement of submission, and does not enter into the review of the application.

The letter of intent is requested by July 1, 1992, and is to be addressed to:

Scientific Review Administrator
Research Training Review Committee
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 550
Bethesda, MD 20892

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441.

The title and number of the announcement must be typed in section 2a on the face page of the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applications must be received on or before August 24, 1992.

REVIEW PROCEDURES

All applications responding to this announcement will be reviewed for scientific and technical merit by the Research Training Review Committee of the Division of Extramural Affairs, NHLBI, followed by a second level review by the National Heart, Lung, and Blood Advisory Council.

AWARD CRITERIA

Applications will compete for available funds with other approved Short-Term Training for Minority Students applications assigned to the NHLBI. The following will be considered in making funding decisions:

- o Scientific and technical merit of the application as determined by peer review
- o Availability of funds
- o Program balance among the research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. Guidelines for this program may be obtained from any of the following:

John Fakunding, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 3C04
Bethesda, MD 20892
Telephone: (301) 496-1724

Fann Harding, Ph.D.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building, Room 5A08
Bethesda, MD 20892
Telephone: (301) 496-1817

Mary Reilly, M.S.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 640A
Bethesda, MD 20892
Telephone: (301) 496-7668

For fiscal and administrative matter contact:

Grants Operations Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A15C
Bethesda, MD 20892
Telephone: (301) 496-7255

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.837, 93.838, and 93.839. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21., No. 17
May 8, 1992

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This publication is also available electronically to institutions via BITNET or INTERNET. Alternative access is through the NIH Grant Line using a personal computer. Contact Dr. John James at 301/496-7554 for details, or send an E-mail message to ZNS@NIHCU.

NOTICES

REMINDER OF RECEIPT DATES

NIH GUIDE, Volume 21, Number 17, May 8, 1992

P.T. 34; K.W. 1002002, 0780000

National Center for Research Resources

This is to remind potential applicants of the single annual receipt dates for two ongoing animal facility improvement programs administered by the Comparative Medicine Program, National Center for Research Resources. June 1 is the single receipt date for the program, "Animal Facility Improvement Programs." October 1 is the single receipt date for the program, "Developing and Improving Institutional Animal Resources." Announcement of these programs, including notification of the future single receipt dates, was last published in the NIH Guide for Grants and Contracts, Vol. 20, No. 39, October 18, 1991, as PA-92-10 and PA-92-09 respectively. Additional copies of these announcements and updated application guidelines, which reflect special instructions to accompany the form PHS 398 (rev. 9/91), may be obtained by sending two self-addressed mailing labels to:

Comparative Medicine Program
National Center for Research Resources
Westwood Building, Room 857
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-5175

PEPTIDE ANTAGONISTS OF LHRH AS GONADOTROPIN INHIBITORS

NIH GUIDE, Volume 21, Number 17, May 8, 1992

RFP AVAILABLE: NICHD-CD-92-17

P.T. 34; K.W. 0750020, 0760060, 0755025

National Institute of Child Health and Human Development

The Contraceptive Development Branch of the Center for Population Research, National Institute of Child Health and Human Development (NICHD), is interested in stimulating further investigations into the design, synthesis, and testing of peptide antagonists of LHRH as gonadotropin inhibitors. Such investigations will also involve the biological evaluation of the peptides, preferably by the contractor. The Contraceptive Development Branch is prepared, however, to evaluate such peptides if the contractor is unable to do so. The goal is to obtain LHRH antagonists that are more potent than those currently available, and are devoid of histamine releasing properties. Proposals merely to collect peptides from various sources and/or only perform biological assays are excluded from consideration at this time. Organizations must have adequate facilities to conduct the proposed peptide program. All responsible sources may submit an offer that shall be considered by the agency. It is anticipated that four cost-reimbursement, incrementally funded type contracts will be awarded under the Request for Proposals (RFP) for a period of two years, beginning December 1, 1992. The Government estimates the effort for each contract to be approximately 3.5 staff years annually.

This announcement is not an RFP. RFP-NICHD-CD-92-17 will be issued on or about May 13, 1992. Proposals will be due approximately 60 days thereafter. Copies of the RFP may be obtained by sending a written request to the address listed below. Please enclose a self-addressed label. Requests may also be made by FAX: (301) 402-0915.

Paul J. Duska, Contracting Officer
Contracts Management Branch
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 610
9000 Rockville Pike
Bethesda, MD 20892

ONGOING PROGRAM ANNOUNCEMENTS

RESEARCH ON CHILDREN OF ALCOHOLICS

NIH GUIDE, Volume 21, Number 17, May 8, 1992

PA NUMBER: PA-92-74

P.T. 34, AA; K.W. 0404003, 0411005, 0710105, 0715095, 0404023

National Institute on Alcohol Abuse and Alcoholism

PURPOSE

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) makes grant awards for basic and applied alcohol research projects. The NIAAA encourages grant applicants to develop knowledge in a wide range of areas relevant to the causes, consequences, diagnosis, prevention, and treatment of alcohol abuse and alcoholism. This program announcement describes areas of research interest that are related to children of alcoholics. The processes for submission and review of a grant application and the terms and conditions for grant support are described also. This announcement is a revision of and replaces an earlier announcement for Research on Children of Alcoholics dated January 1989.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Research on Children of Alcoholics, is related to the priority area of alcohol abuse and alcoholism reduction. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic non-profit and for-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. However, foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) Award (R29). Women and minority investigators are encouraged to apply.

MECHANISMS OF SUPPORT

Research support may be requested through applications for a research grant (R01), small grant (R03), FIRST Award (R29), or an exploratory/developmental grant (R21). Specialized announcements for the FIRST Award Program (R29), the small grant program (R03), and for exploratory/developmental grants (R21) are available from the National Clearinghouse for Alcohol and Drug Information, P.O. Box 2345, Rockville, MD 20852, telephone (301) 468-2600 or 1-800-729-6686.

Applicants for R01s may request support for up to five years. Small grants and exploratory/developmental grants are limited to two years. Applicants for FIRST awards must request five years of support. FIRST awards, small grants, and exploratory developmental grants are not renewable but continuation of the work may be requested through other grant mechanisms.

Grant funds may be used for expenses clearly related and necessary to conduct research projects, including direct costs that can be specifically identified with the project and allowable indirect costs of the institution. Funds may not be used to establish, add a component to, or operate a treatment, rehabilitation, or prevention/intervention service program. Support for research-related treatment, rehabilitation, or prevention services and programs may be requested only for costs required by the research. These costs must be justified in terms of research objectives, methods, and designs that promise to yield generalizable knowledge and/or to make a significant contribution to theoretical concepts.

FUNDS AVAILABLE

Applications received in response to this announcement will compete with other applications assigned to the NIAAA for funding. The amount of funding available will depend on the quality of research applications, appropriated funds, and program priorities at the time of the award. While the NIAAA has not set aside funds for this program, it is estimated that approximately \$500,000 will be available annually for two or three new and/or continuation awards.

RESEARCH OBJECTIVES

Extrapolations from data on drinking practices obtained from household probability surveys suggest that there are approximately 29 million children of alcoholics; an estimated 22 million are 18 years of age or older, and 6.6 million are under the age of 18. Unfortunately, despite the magnitude of this population and the possibility that these individuals may suffer a variety of problems and be at risk for alcoholism themselves, little well-controlled research has been done yet in this area. Descriptive epidemiological investigations and a variety of other kinds of studies are needed.

Scientifically sound research can provide a foundation for the development of effective preventive and early intervention programs to alleviate the potential adverse effects of alcoholism and problem drinking in this group.

Although children of alcoholics are at increased risk for alcoholism, it should be noted that a large percentage of these children do not develop this disorder. Research has suggested different patterns of alcoholism, including one subtype in which the expression of alcoholism requires both genetic vulnerability and a high environmental risk. It is conceivable that some high-risk individuals do not develop alcoholism because of the coping mechanisms they employ. A variety of coping mechanisms have been clinically observed in children of alcoholic parents, and many of these children grow up to be free from alcoholism or other psychopathology. The study of coping mechanisms employed by such "resistant" individuals may be of special value for treatment and prevention programs.

Clinical reports concerning children of alcoholics have described a variety of psychological impairments that they experience in addition to alcohol or drug abuse. Psychological problems noted have included the presence of both major and minor types of psychopathology, impaired self-esteem and reality testing, impaired academic and vocational performance, and susceptibility to a large number of acting-out behaviors, including delinquency and running away. Most of these studies were limited to assessing children who were receiving treatment for their problems or whose parents were being treated for alcoholism. Research is needed to examine a broader spectrum of children of alcoholics. Research in large non-clinical populations might address questions such as the following:

- o What are the psychological characteristics associated with having one or both parents alcoholic? Are these characteristics specific for children of alcoholics or are they similar to those found in offspring of other dysfunctional families?
- o Do children born after a parent's recovery from alcoholism suffer psychological problems at a rate higher than children from families who have not had a past problem with alcoholism? How do their problem rates compare with those of children of active alcoholics? How do they compare with those of children of individuals with other chronic conditions (e.g., schizophrenics or renal dialysis patients)?
- o Are there characteristics of "psychological resilience" that buffer the adverse effects of parental alcoholism on some children? If such characteristics exist, what are they, and can they be developed in other children of alcoholics?
- o Do family factors exist that reduce the risk of problems in children of alcoholics? Do children of male alcoholics have the same problems as children of female alcoholics? How are type and severity of parental alcoholism related to symptoms in children?
- o Are there consistent age-related progressions of problems in children of alcoholics? In other words, do children of alcoholics experience different problems at different ages? Do particular early problems serve as warning signs of later problems? Can effective prevention strategies be developed and implemented for these

at-risk children? What are the positive and negative effects of labeling children at-risk?

o What are the characteristics of individuals who are affiliated with adult children of alcoholics groups? How does the age, race, and sex composition of these groups compare to Alcoholics Anonymous? What are the psychological characteristics of participants in adult children of alcoholics groups?

Studies of the variety of adverse consequences for children of alcoholics may also include the relationship between excessive drinking and sexual abuse of children and of spouses. Research on the role of excessive drinking in other violent behavior directed towards children and spouses is also of particular interest.

Any research project on children of alcoholics may be included under this announcement, and research studies on gender differences and similarities are encouraged.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN RESEARCH

For projects involving human subjects and human materials, ADAMHA/NIH requires applicants to include minorities and both genders in study populations. Racial/ethnic minority and gender differences in human subjects provide valid scientific and public health reasons for requiring that research involving human subjects includes appropriate minority and gender representation. If one gender and/or minorities are excluded or are inadequately represented in this research, a clear compelling rationale for exclusion or inadequate representation must be provided. ADAMHA/NIH will not make awards that do not comply with this policy. Instructions are provided in for PHS 398 (rev. 9/91), Section IV.C.4.

If the required information is not contained within the application, the application will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If there is limited representation, or absence of minority representation or only one gender is represented, AND the scientific justification for the selected study population is inadequate, reviewers will consider this as a scientific weakness or deficiency in the study design and reflect this in the written review statements and in the assigned priority score.

Protection of Human Subjects

The Department of Health and Human Services (DHHS) has regulations for the protection of human subjects and has developed additional regulations for the protection of children. A copy of these regulations (45 CFR 46, Protection of Human Subjects) and those pertaining specifically to children are available from the Office for Protection from Research Risks, National Institutes of Health, Building 31, Room 5B59, Bethesda, MD 20892, telephone (301) 496-7041. Specific questions concerning protection of human subjects in research may be directed to the staff member listed under INQUIRIES.

An applicant organization proposing to conduct non-exempt research involving human subjects must file an "Assurance of Compliance" with the Office for Protection from Research Risks. As part this Assurance, which commits the applicant organization to comply with the DHHS regulations, the applicant organization must appoint an institutional review board that is required to review and approve all non-exempt research activities involving human subjects.

APPLICATION PROCEDURES

Applicants are to use the grant application form PHS 398 (rev. 9/91). The number and title of this announcement, "Research on Children of Alcoholics - PA-92-74," must be typed in item 2a on the face page of the PHS 398 application form.

Application kits containing the necessary forms and instructions (PHS 398) may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following office may be contacted for the necessary application material:

National Clearinghouse for Alcohol and Drug Information
P.O. Box 2345
Rockville, MD 20852
Telephone: (301) 468-2600 or 1-800-729-6686

The signed original and five permanent, legible copies of the completed application must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator must be included with the application.

REVIEW PROCEDURES

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most

discretionary PHS grant programs. Applications received under this announcement will be assigned to an Initial Review Group (IRG) in accordance with established PHS Referral Guidelines. The IRGs, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit. Notification of the review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by an appropriate National Advisory Council. Only applications recommended by a council may be considered for funding.

Application Receipt and Review Schedule

Applications will be accepted and reviewed according to the following schedule:

Receipt Dates New/Renewal	Initial Review	Advisory Council Review	Earliest Start Date
Feb 1/Mar 1*	May/Jun	Sep/Oct	Dec 1
Jun 1/Jul 1*	Oct/Nov	Jan/Feb	Apr 1
Oct 1/Nov 1*	Feb/Mar	May/Jun	Jul 1

* Competing continuation, supplemental, and revised applications are to be submitted on these dates.

Consequences of Late Submission

Applications received after the above receipt dates may be returned to the applicant without review or assigned to the next review cycle if requested by the applicant.

REVIEW CRITERIA

Criteria for scientific/technical merit review of research grant (R01) applications will include the following:

- o The overall scientific and technical merit and significance of the proposed research.
- o The appropriateness and adequacy of the experimental design, including the adequacy of the methodology proposed for collection and analysis of data.
- o The adequacy of the qualifications (including level of education and training) and relevant research experience of the Principal Investigator and key research personnel.
- o The availability of adequate facilities, general environment for the conduct of proposed research, other resources, and any collaborative arrangements necessary for the research.
- o The appropriateness of budget estimates for the proposed research activities.
- o Where applicable, the adequacy of procedures to protect or minimize possible adverse effects on humans, animals, or the environment.
- o Conformance of the application to the NIH and ADAMHA policy on inclusion of women and minorities in study populations.

The review criteria for small grants (R03), exploratory/developmental grants (R21), and FIRST Awards (R29) are contained in the relevant program announcements.

AWARD CRITERIA

Applications recommended by a National Advisory Council will be considered for funding on the basis of overall scientific and technical merit of the research as determined by peer review, program needs and balance, and availability of funds.

INQUIRIES

Potential applicants are encouraged to seek preapplication consultation and may contact either one of the individuals listed below for consultation in preparing an application under this announcement. Direct inquiries relating to program issues to:

Cherry Lowman, Ph.D.
Treatment Research Branch
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
5600 Fishers Lane, Room 14C-20
Rockville, MD 20857
Telephone: (301) 443-0796

Jan Howard, Ph.D.
Prevention Research Branch
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
5600 Fishers Lane, Room 13C-23
Rockville, MD 20857
Telephone: (301) 443-1677

Inquiries relating to fiscal matters are to be directed to:

Joseph Weeda
Chief, Grants Management Branch
Office of Planning and Resource Management
National Institute on Alcohol Abuse and Alcoholism
5600 Fishers Lane, Room 16-86
Rockville, MD 20857
Telephone: (301) 443-4703

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.273. Awards are made under the authority of Sections 301 and 510 of the Public Health Service Act, as amended (42 USC 241 and 290bb). Federal regulations at 42 CFR Part 52, "Grants for Research Projects," and Title 45 CFR Parts 74 and 92, generic requirements concerning the administration of grants, are applicable to these awards. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

RESEARCH ON ALCOHOLISM PATIENT-TREATMENT MATCHING

NIH GUIDE, Volume 21, Number 17, May 8, 1992

PA NUMBER: PA-92-75

P.T. 34; K.W. 0404003, 0413001, 0715129, 0404001, 0755018

National Institute on Alcohol Abuse and Alcoholism

PURPOSE

Current research indicates that alcohol dependence and problem drinking are neither unitary phenomena nor unidimensional syndromes. Instead, there appear to be different types of alcohol-dependent individuals. Individual characteristics other than the kind of alcohol problem also seem to affect treatment outcomes. It is becoming evident that both treatment outcomes and costs can be positively affected by carefully matching patients, by their characteristics, with specific treatments. This announcement seeks research grant applications to investigate the therapeutic impact of matching patients more specifically to various treatments.

This announcement is a revision of "Alcoholism Treatment: Matching Clients to Treatments" (Revised April 1989).

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Research on Alcoholism Patient-Treatment Matching, is related to the priority area of decreasing morbidity and mortality associated with alcohol abuse and alcoholism. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications for alcohol research grants may be made by domestic and foreign, public and private, non-profit and for-profit organizations, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. However, foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) Award. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

Research support may be requested through applications for a research grant (R01), small grant (R03), exploratory/developmental grant (R21) for Alcoholism Treatment Assessment Research, and FIRST Award (R29). Special announcements for exploratory/developmental grants (R21), the FIRST Award program (R29), and the small grant program (R03) are available from the National Clearinghouse for Alcohol and Drug Information as described under APPLICATION PROCEDURES.

Terms and Conditions of Support

Grant funds may be used for expenses clearly related and necessary to conduct research projects including direct costs that can be specifically identified with the project and allowable indirect costs. Funds may not be used to establish, add a component to, or operate a treatment, rehabilitation, or prevention service program. Support for research-related treatment, rehabilitation, or prevention services and programs may be requested only for those particular costs and for that period of time required by the research. These costs must be justified in terms of research objectives, methods, and designs that promise to yield important generalizable knowledge and/or to make a significant contribution to theoretical concepts.

Grants will be administered in accordance with the PHS Grants Policy Statement (rev. October 1990), which is usually available from the office of sponsored research.

FUNDS AVAILABLE

No specific funds are being allocated by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) for this program. Applications received in response to this announcement will compete with others submitted to the NIAAA for funding. The amount of funding available will depend on appropriated funds, quality of research proposals, and program priorities at the time of the award. In FY 1991, the NIAAA awarded two grants relating to this program area, including new and continuation grants, for \$428,000.

RESEARCH OBJECTIVES

This announcement solicits research grant applications that propose to study differences among alcoholism treatment regimens in terms of efficacy and cost effectiveness for different types of patients. Specifically, this announcement seeks research projects that: (1) study the effects of the careful matching of patient variables with treatment and setting variables, (2) develop prediction techniques to identify treatments most suitable for patients at various points in the development of their alcohol dependency or recovery, and/or (3) assess the relative cost effectiveness of different types of treatment and settings for different client types.

Although research on individualizing alcoholism treatment based on patient characteristics is rather new in nature, treatment matching appears promising as a means of improving treatment outcomes. Well-conceived and rigorously designed research is needed to identify specific therapeutic elements that may contribute to favorable outcomes for particular subgroups.

Patient factors of interest include, but are not limited to: type of alcoholism, degree of alcohol dependency, family history of alcoholism, other drug use, psychiatric comorbidities (e.g., depression, panic attacks, antisocial personality), age (adolescent, adult, aged), gender, previous treatment history, neurophysiological status/severity, personality type, general adjustment status, ethnicity, motivation for treatment, patient preference regarding type of intervention, and drinking pattern. Potential treatment variables for patient-treatment matching include: treatment modality, program structure, therapist characteristics (such as perceived empathy, competence, or conceptual level), and treatment setting, among others.

The use of well-established and validated instruments or techniques for assessing patient characteristics and treatment outcomes is recommended. In keeping with this, preference will also be given to applications that include both biochemical and self-report measures of outcome. Even when cost or cost-effectiveness factors are not a direct focus of the study, applicants are urged to collect cost data for the studies, if applicable, and to include an analysis of the comparative costs of the treatments studied in the final report, if relevant. Also, since an important aspect of treatment-effectiveness research is its generalizability to applied treatment programs, applicants are urged to report the percentage of patients who refuse to participate in the study or in a particular intervention. Studies may include patients at more than one facility in order to determine the generalizability of matching strategies. Researchers having access to data sets dealing with the general effectiveness of a treatment intervention variable may also propose research projects that involve secondary data analyses to address the question: What types of patients did particularly well with this intervention and which did poorly? When sample sizes permit, patient and treatment interactions to be studied also might include patient-treatment matches that consider two or more patient characteristics or treatment factors simultaneously (for example, patient emotional stability and locus of control matched to degree of structure in treatment).

While a single study may not be sufficient to collect information from all types of persons seeking alcoholism treatment, applicants may wish to select certain demographic groups (e.g., women, minorities, military personnel, elderly, adolescents) and study them intensively for consideration. Justification for selection of certain groups is necessary, as specified in the following section on "Special Instructions for Inclusion of Women and Minorities as Subjects in Research."

The NIAAA specifically encourages applications that evaluate patient and treatment factors that have already been shown to have some effect on outcome in the treatment of alcoholism, drug dependency, and other behavioral dysfunctions. The variables selected for study should be ones for which a strong clinical rationale or empirical argument can be made regarding their likely contribution to effective patient treatment matching. Studies investigating the appropriateness of pharmacotherapeutic techniques for particular patient types are also of special interest. Studies of matching and treatment techniques for severe chronic alcoholics and other difficult-to-treat categories of alcoholics and alcohol abusers are of special concern as well.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF MINORITIES AND WOMEN AS SUBJECTS IN RESEARCH

Applications for grants and cooperative agreements and proposals for contracts that involve human subjects are required to include minorities and both genders in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions which disproportionately affect them. This policy applies to all research involving human subjects and human materials, and applies to males and females of all ages. If one gender and/or minorities are excluded or are inadequately represented in this research, particularly in proposed population-based studies, a clear compelling rationale for exclusion or inadequate representation should be provided. The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH and ADAMHA recognize that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., American Indians or Alaskan Natives, Asians or Pacific Islanders, Blacks, Hispanics). Investigators must provide the rationale for studies on single minority population groups.

Applications for support of research involving human subjects must employ a study design with minority and/or gender representation (by age distribution, risk factors, incidence/prevalence, etc.) appropriate to the scientific objectives of the research. It is not an automatic requirement for the study design to provide statistical power to answer the questions posed for men and women and racial/ethnic groups separately; however, whenever there are scientific reasons to anticipate differences between men and women, and racial/ethnic groups, with regard to the hypothesis under investigation, applicants should include an evaluation of these gender and minority group differences in the proposed study. If adequate inclusion of one gender and/or minorities is impossible or inappropriate with respect to the purpose of the research, because of the health of the subjects, or other reasons, or if in the only study population available, there is a disproportionate representation of one gender or minority/majority group, the rationale for the study population must be well explained and justified.

The NIH/ADAMHA funding components will not make awards of grants, cooperative agreements, or contracts that do not comply with this policy. For research awards which are covered by this policy, awardees will report annually on enrollment of women and men, and on the race and ethnicity of subjects.

Protection of Human Subjects

The Department of Health and Human Services (DHHS) has regulations for the protection of human subjects and has developed additional regulations for the protection of children. A copy of these regulations (45 CFR 46, Protection of Human Subjects) and those pertaining specifically to children are available from the Office for Protection from Research Risks, National Institutes of Health, Building 31, Room 5B59, Bethesda, MD 20892, telephone (301) 496-7041. Specific questions concerning protection of human subjects in research may be directed to the staff member listed under INQUIRIES.

An applicant organization proposing to conduct nonexempt research involving human subjects must file an "Assurance of Compliance" with the Office for Protection from Research Risks. As part of this Assurance, which commits the applicant organization to comply with the DHHS regulations, the applicant organization must appoint an institutional review board, which is required to review and approve all nonexempt research activities involving human subjects.

APPLICATION PROCEDURES

Applicants are to use the grant application form PHS 398 (rev. 9/91). The number and title of this announcement, "Research on Alcoholism Patient-Treatment Matching - PA-92-75," must be typed in item 2a on the face page of the PHS 398 application form.

Application kits containing the necessary forms and instructions (PHS 398) may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following office may be contacted for the necessary application material:

National Clearinghouse for Alcohol and Drug Information
P.O. Box 2345
Rockville, MD 20852
Telephone: (301) 468-2600 or 1-800-729-6686

The signed original and five permanent, legible copies of the completed application must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary PHS grant programs. Applications received under this announcement will be assigned to an Initial Review Group (IRG) in accordance with established PHS Referral Guidelines. The IRGs, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit. Notification of the review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by an appropriate National Advisory Council. Only applications recommended by a Council may be considered for funding.

Application Receipt and Review Schedule

Applications will be accepted and reviewed according to the following schedule:

Receipt Dates New/Renewal	Initial Review	Advisory Council Review	Earliest Start Date
Jun 1/Jul 1*	Oct/Nov	Jan/Feb	Apr 1
Oct 1/Nov 1*	Feb/Mar	May/Jun	Jul 1
Feb 1/Mar 1*	May/Jun	Sep/Oct	Dec 1

* Competing continuation, supplemental, and revised applications are to be submitted on these dates.

Consequences of Late Submission

Applications received after the above receipt dates are subject to assignment to the next review cycle or may

be returned to the investigator without review if requested by the applicant.

Review Criteria

Criteria for scientific/technical merit review of applications for research grants (R01) will include the following:

- o The overall scientific and technical merit and significance of the proposed research.
- o The appropriateness and adequacy of the experimental design including the adequacy of the methodology proposed for collection and analysis of data.
- o The adequacy of the qualifications (including level of education and training) and relevant research experience of the Principal Investigator and key research personnel.
- o The availability of adequate facilities, general environment for the conduct of proposed research, other resources, and any collaborative arrangements necessary for the research.
- o The appropriateness of budget estimates for the proposed research activities.
- o Where applicable, the adequacy of procedures to protect or minimize possible adverse effects on humans, animals, or the environment.
- o Conformance of the application to the ADAMHA/NIH policy on inclusion of women and minorities in study populations.

The review criteria for small grants (R03), exploratory/developmental grants (R21), and FIRST Awards (R29) are contained in the specialized announcements that are available from the National Clearinghouse for Alcohol and Drug Information as described under APPLICATION PROCEDURES.

AWARD CRITERIA

Applications recommended by a National Advisory Council will be considered for funding on the basis of overall scientific and technical merit of the research as determined by peer review, program needs and balance, and availability of funds.

INQUIRIES

Potential applicants are encouraged to seek preapplication consultation and may contact the individual listed below for consultation in preparing an application under this announcement. Direct inquiries to:

Margaret Mattson, Ph.D.
Treatment Research Branch
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
5600 Fishers Lane, Room 14C-20
Rockville, MD 20857
Telephone: (301) 443-0796

Inquiries relating to fiscal matters may be directed to:

Elsie Fleming
Grants Management Branch
Office of Planning and Resource Management
National Institute on Alcohol Abuse and Alcoholism
5600 Fishers Lane, Room 16-86
Rockville, MD 20857
Telephone: (301) 443-4703

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.273. Awards are made under the authority of Sections 301 and 510 of the Public Health Service Act, as amended (42 USC 241 and 290bb). Federal regulations at 42 CFR Part 52, "Grants for Research Projects," and Title 45 CFR Parts 74 and 92, generic requirements concerning the administration of grants, are applicable to these awards. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

AIDS-ASSOCIATED KAPOSI'S SARCOMA

NIH GUIDE, Volume 21, Number 17, May 8, 1992

PA NUMBER: PA-92-76

P.T. 34; K.W. 0715008, 0715035, 0710100, 0740015, 0760020

National Cancer Institute
National Institute of Allergy and Infectious Diseases

PURPOSE

The Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI) and the Division of Acquired Immunodeficiency Syndrome (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID) invite applications from interested investigators to perform innovative correlative laboratory studies of relevance to new and ongoing AIDS-Kaposi's sarcoma clinical trials or to develop new therapies for the treatment of AIDS-Kaposi's sarcoma with laboratory correlations. This Program Announcement (PA) is designed to promote collaborations and interactions among researchers from a variety of basic and clinical disciplines to facilitate better treatment and management of AIDS-Kaposi's sarcoma patients.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, AIDS-Associated Kaposi's Sarcoma, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments and eligible agencies of the Federal government. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) (R29) Award. Applications from minority individuals and women are encouraged. Applications from single or multiple institutions (individual institutions, consortia, and cancer centers) with established clinical, laboratory, and statistical resources are encouraged.

MECHANISM OF SUPPORT

Awards will be made as investigator-initiated research grants (R29, R01 and interactive R01s) in accordance with PHS policies applicable to research project grants. A description of an interactive R01 application is published in the NIH Guide (Vol. 21, No. 1, January 10, 1992) under PA-92-29. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No.(OASH) 90-50,000, revised October 1, 1990.

RESEARCH OBJECTIVES

Summary

Kaposi's sarcoma (KS) is one of the malignancies most frequently seen in AIDS patients; however, the etiology of KS in AIDS patients remains unclear. The precise relationship of KS to the underlying immunodeficient state in patients with HIV infection also remains unclear. The most prominent clinical feature of KS in HIV-positive patients is the aggressiveness of the disease. KS in AIDS patients is associated with extensive involvement of skin and mucous membranes, early dissemination to lymph nodes, impressive development of extreme lymphedema, even in the absence of bulky adenopathy, and rapid spread to visceral organs, including lungs and gastrointestinal tract. Although rapid clinical progression and short median survival have been the rule, some patients have survived for many years with disease limited to the skin. Certain clinical and laboratory features, such as presence of unexplained fever, night sweats, weight loss, and significant T4 lymphocytopenia, have been identified as indicators of poor prognosis. Various therapeutic interventions have been employed resulting in partial and complete remissions but with no significant improvement in the survival of these patients. High-dose recombinant interferon alpha has produced response rates in approximately 30 percent of treated patients. Likewise, vinblastine has produced similar response rates. Both of these therapies have substantial toxic side effects. The purpose of this PA is to foster collaborative interactions between laboratory scientists and clinicians to precisely characterize the molecular and genetic characteristics of AIDS- Kaposi's sarcoma or to devise more effective management of this disease. Laboratory research efforts and novel therapies ready to be applied in clinical situations and innovative clinical applications are solicited. It is hoped that the results obtained from studying AIDS-Kaposi's sarcoma patients will increase the understanding of the biology of this disease and will assist the development of more effective treatment in the general population of KS patients and patients with other proliferative diseases.

Some examples of clinical studies and their correlative laboratory studies that would qualify are: (1) pharmacokinetic and pharmacodynamic measurements leading to novel means of combining retroviral and antitumor therapies; (2) biological response modifiers in combination with cytotoxic and radiation therapy with immune function studies; (3) molecular characterization of oncogenes and growth factors for the development of new anti-growth factor or anti-sense therapies. Investigators are not limited to the above examples of potential studies. Other scientific approaches may be proposed.

The NCI recognizes that research in AIDS-Kaposi's sarcoma is technically difficult to conduct because of the complexity of this disease and the relatively limited availability of study subjects at any single institution. Thus, the NCI is encouraging the submission of grant applications for research relevant to this PA in the context of multi-institutional efforts under the interactive R01 mechanism (see PA-92-29).

Objectives

The aims of this initiative are two-fold: (1) to support innovative correlative laboratory studies relevant to AIDS-Kaposi's sarcoma clinical trials and (2) to stimulate development of innovative AIDS-Kaposi's sarcoma clinical studies with laboratory correlations so as to foster the development of interactions between basic science laboratories and clinicians performing these clinical trials.

STUDY POPULATION

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF FEMALES AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in the Research Plan, 1-4 AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the deadlines as indicated in the application kit for AIDS-related research (January 2, May 1, and September 1).

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441. The title and number of the announcement must be typed in Section 2a on the face page of the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines.

Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Roy S. Wu
Program Director, Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

Dr. Giorgio Galletto
NIAID Program Director
National Institute of Allergy and Infectious Diseases
Control Data Building, Room 2C32
Bethesda, MD 20892
Telephone: (301) 496-0700
FAX: (301) 480-5703

Direct inquiries regarding fiscal matters to:

Ms. Carolyn Mason
Grants Management Specialist
National Cancer Institute
Executive Plaza South, Room 242
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 59
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.395, Cancer Treatment Research, No. 93.855, Immunology, Allergy, and Immunologic Research, and No. 93.856, Microbiology and Infectious for Research. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NUTRIENT INFLUENCE ON GENE REGULATION AND EXPRESSION

NIH GUIDE, Volume 21, Number 17, May 8, 1992

PA NUMBER: PA-92-77

P.T. 34; K.W. 0765015, 0710095, 0765020, 1002008, 0765010, 0760025

National Institute of Diabetes and Digestive and Kidney Diseases
National Heart Lung and Blood Institute
National Institute of Child Health and Human Development

PURPOSE

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Heart Lung and Blood Institute (NHLBI), and the National Institute of Child Health and Human Development (NICHD) are interested in receiving research grant applications for support of research on dietary factors that control or regulate specific molecular and genetic functions. Applications covering a broad range of activities in this area, including both basic and clinical research, are encouraged. It is expected that regardless of approach, all studies will be focused on normal and/or abnormal control of gene regulation and expression. This type of announcement is issued in order to encourage investigator-initiated research projects in these areas of special programmatic interest.

The Public Health Service (PHS) is committed to achieve the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Nutrient Influence on Gene Regulation and Expression, is related to the priority areas focusing on the roles of specific dietary factors in the etiology and prevention of chronic diseases and obesity. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) Award (R29). Applications from minority individuals and women are encouraged.

MECHANISMS OF SUPPORT

Support of this program will be by research project grants (R01) and FIRST Awards (R29).

RESEARCH OBJECTIVES

The National Institutes of Health (NIH) supports basic and clinical studies related to the requirements, bioavailability, and metabolism of nutrients and other dietary components at the organ, cellular, and subcellular levels in normal and diseased states. Specific areas of research interest include the understanding of the physiological, biochemical and molecular functions and mechanisms of action/interaction of nutrients within the body.

This announcement is intended to stimulate research on dietary factors and related metabolic interactions that have direct or indirect nutrient influence on specific gene regulation and expression. This would require interdisciplinary efforts focusing on interactions of nutrition, molecular biology, and metabolism. Recent studies indicate that this is an emerging area, rich with opportunities, but in need of additional support for further development of research efforts. It appears that nutritional factors, e.g., various vitamins regulated via dietary intake can interact with other regulatory networks, such as tissue-specific, developmental, and hormonal factors, as well as dietary fat or carbohydrate, to regulate gene expression. Other studies have demonstrated regulation of apoprotein gene expression by sucrose-rich diet, nutritional regulation of gene expression in lipogenesis, and suppression of fatty acid synthase transcription by polyunsaturated fatty acids. More advanced studies focus on dietary protein control of intestinal hormone gene expression. Significant regulation appears to be at the level of transcription, with controlled modulation of messenger RNA levels. However, basic mechanisms underlying the influence of dietary factors and related metabolites on gene transcription need further study. In addition to studies focusing on mechanisms controlling gene regulation by dietary factors, support is also needed for work on the interactions between genetic factors and nutrition. In particular, work is encouraged on mechanisms influenced by hyper- and hypo-responsiveness to diet. This may be critical in evaluating outcomes of dietary therapy regimens.

Other, specific examples of research objectives appropriate for inclusion in applications responsive to this program announcement include:

- o studies on retinoic acid regulation of adipocyte gene expression;
- o studies of dietary antioxidant/oxidant factors that affect DNA structure and function;
- o studies on influence of cholesterol and triglyceride levels in regulation of LDL receptor gene and apolipoprotein gene expression in the liver and GI tract;
- o studies on nutrient control of lipoprotein lipase gene expression;
- o studies of factors that mediate the protein synthetic response to nutrient intake;
- o studies on interactions of vitamins and other dietary factors with nuclear receptors;
- o studies of gastrointestinal hormone gene regulation by specific nutrients;
- o studies of dietary factors controlling expression of transferrin receptor and other proliferation-related genes.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions that disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator must be included with the application.

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441. The title and number of the announcement must be typed in line 2a on the face page of the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by an appropriate national advisory council or board. Applications for supplements to ongoing awards will be reviewed according to procedures applicable to the mechanism of the ongoing award.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Direct inquiries regarding programmatic issues to:

Michael K. May, Ph.D.
Director, Nutrient Metabolism Program
Division of Digestive Diseases and Nutrition
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A18A
Bethesda, MD 20892
Telephone: (301) 496-7121
FAX: (301) 402-1278

Direct inquiries regarding fiscal matters to:

Ms. Paulette Badman
Grants Management Specialist
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 639
Bethesda, MD 20892
Telephone: (301) 496-7467
FAX: (301) 496-9721

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.837, 93.848, and 93.865. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SOCIAL WORK RESEARCH DEVELOPMENT CENTERS

NIH GUIDE, Volume 21, Number 17, May 8, 1992

PA AVAILABLE: PA-92-78

P.T. 34; K.W. 0417000, 0715095, 0715129

National Institute of Mental Health

THE PROGRAM ANNOUNCEMENT (PA) DESCRIBED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE PA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The purpose of this announcement is to encourage the development of social work research in all areas of mental health research. The goal is to strengthen the institutional infrastructure and to develop the capability of individual faculty members to do mental health research.

The Social Work Research Development Centers program is in response to recommendations of the National Advisory Mental Health Council and of a special Task Force on Social Work Research, which analyzed the current state of research education, research resources, and research development in social work.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Social Work Research Development Centers, is related to the priority areas of mental health objective 6. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Domestic public and private universities and/or colleges that award graduate degrees in social work/social welfare may apply, but the application may include undergraduate programs in social work.

MECHANISM OF SUPPORT

Grants awarded in the SWRDC program will use the Resource-Related Research Projects (R24) mechanism designed to enhance the capability of resources to serve biomedical and behavioral research.

FUNDS AVAILABLE

Applications will compete with all other investigator-initiated applications. For the first year of a grant, it is expected that the Infrastructure Improvement Plan component will average between \$200,000 to \$300,000; specific budgets for each Research Enhancement Proposal must be justified on a project-by-project basis.

RESEARCH OBJECTIVES

Applicant institutions must describe a comprehensive and coherent plan of improvement to the institution's

current research environment that will enhance the capability of investigators at the institution to conduct extramurally supported mental health research. The plan must focus on one or more research core areas that will be addressed by SWRDC study teams.

SWRDC Program Specifications/Application Characteristics

The applicant must provide a plan for the proposed SWRDC that includes: (1) an assessment of the current institutional and faculty capacity to conduct mental health research; (2) identification of unmet needs; and (3) a description of the activities to develop the institutional infrastructure and faculty capacity to conduct mental health research. The overall SWRDC plan must include both an Infrastructure Improvement Plan and one or more Research Enhancement Proposals.

I. Infrastructure Improvement Plan must address major scientific knowledge gaps and needs in mental health. Each SWRDC must define one or more research core area(s) that will be addressed by the SWRDC study teams. Core Research Areas include: the etiology, pathophysiology, diagnosis, prevalence, clinical course, treatment, and prevention of mental disorders; biomedical, behavioral, and social research to develop and expand basic knowledge relevant to the understanding, prevention, and treatment of mental illness; mental health services for individuals with severe mental disorders; child and adolescent mental health services; cultural, racial, and ethnic experiences that influence mental health outcomes. Separate descriptions must be provided for each of the major core areas applicable to the proposed SWRDC. Each Infrastructure Improvement Plan should include descriptions of individual pilot and early developmental research projects to be supported by the Center.

Strategic Plan: A description of the institution's strategic plan to improve the quality of its mental health research and educational programs. Details of the role that the SWRDC will play in achieving its objectives; the rationale for the selection of specific improvement strategies and their relation to the long- term institutional goals; and the improvements anticipated as a result of an SWRDC award should be addressed.

II. Research Enhancement Proposals: One or more individual research enhancement proposals that are directly linked to the overall infrastructure improvement plan must be included with a SWRDC application. Projects should be well thought out and include a detailed research proposal, although it is recognized that the initial projects may include some that are developmental projects.

Leadership: The SWRDC Program Director is responsible for the scientific and technical direction of the SWRDC program. He/she should be a scientist with appropriate training and experience and should have the authority and support of the institution necessary to effectively implement the plan.

An overall SWRDC budget is required. In addition, separate budget pages must be prepared for the SWRDC Infrastructure Improvement Plan and for each SWRDC Research Enhancement Proposal.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF ADAMHA POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN RESEARCH STUDY POPULATIONS

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

Applicants are to use the Public Health Service research grant application form PHS 398 (rev. 9/91). The number and title of this announcement, PA-92-78 "Social Work Research Development Centers: Infrastructure Improvement Plan" or "Social Work Research Development Centers: Research Enhancement Proposal" must be typed in item number 2a on the face page of the PHS 398 application form.

Applications for a SWRDC must include two separate components: (1) an Infrastructure Improvement Plan and (2) one or more Research Enhancement Proposals. For the purposes of the page limitations of sections 1 through 4 of PHS 398, the overall Infrastructure Improvement Plan may not exceed 25 pages. Each Research Enhancement Proposal is limited to an additional 25 pages each for the sections 1 through 4. Applications exceeding the page limits will be returned.

The signed original and five permanent legible copies of the completed application must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

The due dates are June 1, October 1, and February 1.

REVIEW CONSIDERATIONS

Applications will be reviewed for scientific and technical merit by an initial review group (IRG) composed primarily of non-Federal scientific and technical experts. Second level review is by the appropriate national advisory council; review by the council may be based on policy considerations as well as scientific merit. By law, only applications recommended by the council may be considered for funding. Summary statements of IRG discussions are sent to applicants as soon as possible following IRG review.

Review Criteria

The review criteria are the overall scientific and technical merit of the SWRDC Infrastructure Improvement Plan and each of the SWRDC Research Enhancement Proposals. The IRG will review and critique each component separately. A priority score reflecting the technical and scientific merit of the application overall will be assigned by the reviewers.

Criteria for scientific/technical merit review of applications for the Infrastructure Improvement Plan will include: quality and significance of the overall plan to the goals of this announcement, including the likelihood that it will result in the development of a strong research capacity; appropriateness and relevance of the proposed improvement strategies to the school's and institution's needs; their compatibility with SWRDC objectives; and their potential for effecting significant and lasting improvements in academic mental health research competitiveness; the nature, amount, and duration of the non-Federal commitment to the plan (e.g., financial, personnel, facilities); quality and significance of the planned core substantive areas of mental health research; adequacy of the theoretical and conceptual framework for the research as well as appropriateness of research approaches and methodology for each area.

Criteria for Research Enhancement Proposals will include: significance of the research to mental health; adequacy of the theoretical and conceptual framework of the proposed research project and appropriateness of research; scientific quality of the project design; relationship of the research project to the overall SWRDC program; appropriateness of the budget.

AWARD CRITERIA

Applications recommended by the appropriate national advisory council will be considered for funding on the basis of overall scientific and technical merit of the research as determined by peer review, program needs and balance, and availability of funds.

INQUIRIES

Direct inquiries concern programmatic matters to:

Kenneth G. Lutterman, Ph.D.
Associate Director for Research Training and Resource Development
Division of Applied and Services Research
National Institute of Mental Health
5600 Fishers Lane, Room 18C-26
Rockville, MD 20857
Telephone: (301) 443-3685

Leonard Mitnick, Ph.D.
Chief, Basic Prevention and Behavioral Medicine Research Branch
Division of Basic Brain and Behavioral Sciences
National Institute of Mental Health
5600 Fishers Lane, Room 11C-06
Rockville, MD 20857
Telephone: (301) 443-4337

Leonard Lash, Ph.D.
Associate Director for Research Training and Resource Development
Division of Clinical Research
National Institute of Mental Health
5600 Fishers Lane, Room 10-95
Rockville, MD 20857
Telephone: (301) 443-3264

Inquiries pertaining to grants management should be directed to:

Steven Hudak
Chief, Grants Management Section
National Institute of Mental Health
5600 Fishers Lane, Room 7C-23
Rockville, MD 20857
Telephone: (301) 443-4456

ERRATUM

NATIONAL RESEARCH SERVICE AWARD INSTITUTIONAL TRAINING GRANTS

NIH GUIDE, Volume 21, Number 17, May 8, 1992

PA NUMBER: PA-92-31

P.T. 44; K.W. 0720005, 0404003, 0404009, 0715095, 1014006

Alcohol, Drug Abuse, and Mental Health Administration

On January 17, 1992, the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) published the updated

National Research Service Awards (NRSA) for Institutional Training Grants announcement in the NIH Guide for Grants and Contracts (Vol. 21, No. 2). This program announcement permits, for the first time, the possibility of research recruitment positions on institutional training grants. The purpose of this notice is to clarify the guidance contained in the announcement regarding the use of the recruitment positions (see RESEARCH RECRUITMENT). The positions are subject to the same constraints regarding short-term training positions, and appointments may not exceed three months (PHS Act, Section 487(d)(4)).

Also, while not immediately subject to the payback requirement because the time spent in such positions will usually total less than 12 months, the time is accrued with any future NRSA support in calculating the total service obligation (see PAYBACK REQUIREMENT and CONDITIONS OF AWARD). The candidates for these positions must, therefore, be advised of the service payback requirement before an appointment to the training grant is offered. This obligation requires that any NRSA support in excess of 12 months is to be repaid by an equal period of health-related research or health-related teaching (see 42 CFR 66.110).

These research recruitment candidates, like other trainees appointed to the training grant, must complete and return to the ADAMHA a Statement of Appointment Form (Form PHS 2271, rev. 10/91) and a Payback Agreement Form (Form PHS 6031, rev. 10/91). These forms must be completed and returned at the beginning of each appointment and reappointment. At the end of each appointment, a Termination Notice (Form PHS 416-7, rev. 10/91) must be completed and returned to the ADAMHA. Specific information about the NRSA service payback requirement is available in the Guidelines for NRSA Individual Awards - Institutional Grants, NIH Guide for Grants and Contracts, Vol. 13, No. 1, January 6, 1984.

INQUIRIES

Questions regarding this notice may be referred to:

Dr. Jane A. Taylor
Research Training Officer
Alcohol, Drug Abuse, and Mental Health Administration
Room, 13-99, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-1596

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Vol. 21, No. 18
May 15, 1992

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INDEX: DIABETES, DIGESTIVE, KIDNEY DISEASES; CHILD HEALTH, HUMAN DEVELOPMENT

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NOTICES OF AVAILABILITY (RFPs AND RFAs)

RESEARCH TRAINING AND CAREER DEVELOPMENT AWARDS IN NUTRITION AND OBESITY RESEARCH

NIH GUIDE, Volume 21, Number 18, May 15, 1992

RFA AVAILABLE: DK-92-19

P.T. 34, 44; K.W. 0710095, 0715145, 0785035

National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Child Health and Human Development

Letter of Intent Receipt Date: September 18, 1992
Application Receipt Date: October 16, 1992

NOTE: THE FULL TEXT OF THE REQUEST FOR APPLICATIONS (RFA) SHOULD BE REQUESTED - SEE INQUIRIES SECTION.

PURPOSE

The Division of Digestive Diseases and Nutrition of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute of Child Health and Human Development (NICHD) invite applications for Individual National Research Service Award applications (F32s), Clinical Investigator Award applications (K08s), and Physician Scientist Award applications (K11s) in the broad areas of nutrition, nutrient metabolism, obesity, and related research. The intent of this RFA is to provide research training and career development support for individuals with a strong commitment to a research career in the areas of nutrition, nutrient metabolism, obesity, eating disorders, energy metabolism/regulation, and maternal-fetal, infant, and childhood nutrition.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Research Training and Career Development Awards in Nutrition and Obesity Research, is related to the priority area of nutrition. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

Applicants applying for Physician Scientist (K11) and Clinical Investigator (K08) awards must have completed, by the time an award would be activated, a residency in internal medicine, surgery, or pediatrics. Applicants applying for an individual NRSA fellowship (F32) must have received the Ph.D., M.D., or equivalent degree prior to the beginning date of the appointment.

MECHANISM OF SUPPORT

Support of this program will be through the Individual National Research Service Award (F32), the Physician Scientist Award (K11), and the Clinical Investigator Award (K08).

Responsibility for the planning, direction, and implementation of the proposed project will be that of the applicant in conjunction with his/her sponsor(s). Except as otherwise stated in this announcement, awards will be administered under PHS grants policy as stated in the PHS Grants Policy Statement. F32 applicants should be aware that, prior to an award being made, they must sign an agreement that they will fulfill the legislatively mandated payback requirements. More information on payback may be obtained from the Program Directors listed below. (see INQUIRIES)

Grant funds are for research training and career development only, and may not be used for the support of clinical training or clinical services. Such subspecialty activities must be supported from other funding sources.

This RFA is a one-time solicitation. The total requested project period for F32 applications submitted in response to this RFA may not exceed three years; the total requested project period for K08 and K11 applications may not exceed five years. The earliest possible award date will be July 1, 1993.

Potential candidates for F32 awards must be citizens or non-citizen nationals of the United States or its possessions and territories or must have been lawfully admitted to the United States for permanent residence at the time of the application.

FUNDS AVAILABLE

For FY 1993, the NIDDK and the NICHD each plan to make two to three K awards and four to six F32 awards for applications submitted in response to this RFA. However, this funding level is dependent upon the receipt of a sufficient number of applications of high scientific merit. Stipend levels for the NRSA F32 awards are in accordance with those established by the PHS. Salary support for K awards is limited to \$50,000 per year plus either \$10,000 or \$20,000 per year for other expenses, depending upon the mechanism. Although this program is provided for in the financial plans of the NIDDK and the NICHD, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The objective of this solicitation is to increase the number of physicians and basic scientists who can conduct high-quality research in the areas of nutrition and obesity, compete successfully for NIH grant support, and provide leadership in the areas of clinical nutrition/obesity research. It is particularly important to increase the number of underrepresented minority persons and women being trained to pursue research careers and provide leadership in the areas of nutrition and obesity.

Potential applicants are encouraged to read the guidelines for each mechanism and to identify the most appropriate mechanism for their needs and experience. Guidelines are available from the Office of Grants Inquiries, telephone (301) 496-7441.

SPECIAL REQUIREMENTS

Investigators receiving support under any of the award mechanisms offered here also may be enrolled in a medical or surgical subspecialty training program that relates to the nutrition/obesity program of the NIDDK and the NICHD. However, a full-time commitment to research training is required.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

REVIEW CONSIDERATIONS

Applications received in response to this RFA will first be reviewed for scientific and technical merit by an initial review group (IRG) convened by the Review Branch, Division of Extramural Program Activities, NIDDK. Following this initial review, the applications will be given a secondary review by either the NIDDK and NICHD Advisory Councils (K awards) or by the staff of the Division of Digestive Diseases and Nutrition and the NICHD (F32 awards). Applications not recommended for further consideration by the IRG will not undergo secondary review.

The general review criteria for applications received in response to this RFA are the same as those for unsolicited fellowship and career development award applications.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for the K awards. The fellowship application form PHS 416-1 (rev. 4/89) is to be used in applying for the F32 awards. These forms are available from most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 496-7441.

LETTER OF INTENT

Letters of intent are requested by September 18, 1992. Contents should include only a descriptive title of the proposed research, the name, address, and telephone number of the applicant, the name of the sponsor, the names of all participating institutions, and the number and title of the RFA in response to which the application is being submitted. A letter of intent is not required, is not binding, and does not enter into the review of subsequent applications.

A letter of intent is to be sent to:

Chief, Review Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 605
Bethesda, MD 20892
Telephone: (301) 496-7083

INQUIRIES

Direct requests for the RFA and inquiries regarding programmatic issues to:

Judith M. Podskalny, Ph.D.
Director, Research Training and Career Development Program
Division of Digestive Diseases and Nutrition
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A15
Bethesda, MD 20892
Telephone: (301) 496-7455

or

Ephraim Y. Levin, M.D.
Medical Officer
National Institute of Child Health and Human Development
Executive Plaza North, Room 637
Bethesda, MD 20892
Telephone: (301) 496-5593

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93-848 and No. 93-855. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52, 42 CFR 66, and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

HOME HEALTH CARE AND SUPPORTIVE SERVICES FOR OLDER ADULTS

NIH GUIDE, Volume 21, Number 18, May 15, 1992

PA NUMBER: PA-92-79

P.T. 34; K.W. 0730000, 0730050, 0710010, 0785130, 0403004, 0710030

National Institute on Aging
National Center For Nursing Research
Agency for Health Care Policy and Research

PURPOSE

The National Institute on Aging (NIA), the National Center for Nursing Research (NCNR), and the Center for General Health Services Extramural Research, Agency for Health Care Policy and Research (AHCPR), invite qualified researchers to submit applications to investigate the nature, use, and outcomes of different types of in-home health and supportive services. In-home health care and supportive services (hereafter called home care) are defined broadly to include post-acute and long-term health care and social services provided at home. This definition excludes nursing homes but includes individual residences and the wide range of community-based residential settings (e.g., assisted living facilities) where supportive services and specialized environments

enable a dependent individual to remain in the community for as long as possible. Research is encouraged on home care in general or on particular types of care (e.g., high technology home care; skilled home health care; low technology/custodial care).

This program announcement supplements but does not replace earlier NIA program announcements on related topics such as: Aging and Formal Health Care (NIH Guide for Grants and Contracts, Vol. 16, No. 19, June 1987) and Economics of Aging, Health, and Retirement (NIH Guide for Grants and Contracts, Vol. 20, No. 15, April 1991). It also complements an earlier Program Note, "Research Agenda on Home Health Care" by the AHCPR (September 1988). Also relevant is the forthcoming report by the NCNR on Long-Term Care of Older Persons.

The NIA was established to conduct and support research and training on the biomedical, social, and behavioral aspects of the aging process, as well as diseases and other special issues and needs of older people. In line with the Congressional mandate for both medical and non-medical research, long-term care needs of older people and their families is a major priority. The NIA is specifically interested in social and behavioral research on the interaction between older people and their caregivers with the health care system, the linkages between formal and informal care, and the structure, processes, and outcomes of new models of care. Of particular interest is research on home care and supportive services including high technology care, skilled home health care, low technology/custodial care, respite care, and board and care.

The NCNR supports basic and clinical research and research training in patient care relevant to nursing including studies involving home health care and other community-based settings. The major NCNR emphases in building the science related to long-term care in the home have been on the processes and outcomes of care including the testing of intervention strategies to encourage independence, facilitate management of commonly experienced symptoms or health problems, prevent the onset of disabilities in those who are chronically ill, improve functional status and quality of life, maintain caregiver and other family support mechanisms, and facilitate transitions between health care settings and home.

The AHCPR was created to enhance the quality, appropriateness, and effectiveness of health care services and access to such services. The Center for General Health Services Extramural Research (CGHSER) supports multidisciplinary extramural research, demonstrations, and evaluation activities on a broad range of health service research and health care technology issues. Studies focus on improvements in clinical practice, delivery, cost, quality, and access to care. Research on the elderly at CGHSER deals with issues of the organization, delivery, quality, cost, and financing of health services and the role of primary care in long-term care.

Approximately seven million older Americans require assistance with basic tasks of daily living, a number that is expected to increase dramatically as the baby boom generation ages. Though nursing home care is often equated with long-term care, it is but one part of the long-term care continuum. For every person who is institutionalized, an estimated four or more persons in the community require some form of long-term care. The burgeoning long-term care needs of an aging society and less restrictive eligibility requirements for Federal reimbursement have fueled the expansion of the home-care industry.

Care for dependent, older Americans living in the community is a priority area needing the attention of researchers, planners, practitioners, and policy analysts. The Bi-partisan Commission on Comprehensive Health Care (The Pepper Commission) called for substantial increases in long-term care research. The Commission emphasized the need for intensified research on home and community-based care to guide programmatic and policy decisions and to strengthen the current health care system.

Due to an interest in cost-containment of health care services, home care has been proclaimed to be a "cost-effective" alternative to institutionalized care. Yet, existing research on home care simply does not provide an adequate basis for policy and program development. Previous studies of cost-effectiveness of in-home and community-based care have been limited by inconsistencies in definitions of services and inadequate data sources. The resulting contradictory cost-effectiveness studies point to the need for further study on this issue and the need for studies focusing on broader quality of life outcomes.

In collaboration with the Administration on Aging, the NIA sponsored a conference in 1990 focussing on in-home care to identify a research agenda in this area. A detailed summary of identified research concerns is available by writing the National Institute on Aging (see INQUIRIES). In an edited volume on In-Home Care for Older People (Ory and Duncker, 1992), the authors identified three areas highlighted at the conference that need immediate attention: (1) the use of in-home services for older people with different functional needs; (2) the effectiveness of different types or packages of services for different populations, and (3) the coordination (or lack of coordination) of in-home services with physician-provided care. In addition, the significant contributions made by family and friends, the burdens experienced by families providing care, and the need for better integration and coordination of services and care providers across the total continuum of health and social care were issues requiring further investigation.

The lack of a clear conceptualization of home and community-based, long-term care has been a major research obstacle. There is a need for further development of theoretical concepts, including definitions of home care and the boundaries between home care and institutional care. To increase current understanding of home care, it is necessary for investigators to begin to specify variations in the nature and types of care currently used by older adults; to examine clinical strategies and other processes of care on different populations; and to determine the effects of different settings of home and community-based care. More attention is needed on the quality of life and functional outcomes that are of crucial concern to older people and their families. Cost questions also need to be considered in research on in-home health care and other community-based residential care alternatives.

Research is encouraged that specifies the broad conceptual boundaries of home care and gives the field a strong base of data and methodologies. Advances will come through an awareness of the need to draw upon

interdisciplinary expertise in nursing, medicine and other clinical sciences, behavioral sciences, and health service aspects of health and aging. For example, current models of health care utilization can be expanded to pay more attention to the complex interactions of clinical and social influences. Similarly, researchers are urged to design innovative sampling strategies for minimizing typical methodological problems such as population selection bias. Researchers should also be sensitive to all participants in the care process, including clients, their families, and/or other informal care providers, as well as the potential for variability across cultural, ethnic, or gender lines.

HEALTHY PEOPLE

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Home Health Care and Supportive Services for Older Adults, is related to the priority area of educational and community based programs. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENT

Applications for research grants may be made by domestic and foreign, public and private, for-profit and non-profit organizations, such as universities, colleges, hospitals, and laboratories. Women and minority investigators, in particular, are encouraged to apply. Foreign applicants are not eligible for the First Independent Research Support and Transition (FIRST) (R29) awards.

MECHANISMS OF SUPPORT

The primary mechanisms for support of research under this program announcement are the research project grant (R01), and FIRST Award (R29). Applicants are advised to contact the program staff of the NIA, the NCNR, or the AHCPR for further information on levels and duration of support. The AHCPR does not support the FIRST Award.

RESEARCH OBJECTIVES

This announcement seeks grant applications for studies on in-home health care and supportive services to increase understanding of this growing segment of the health care industry. It is anticipated that research funded under this initiative will contribute to the scientific base for informed policy recommendations and changes. Utilization and availability of in-home health care and supportive services, process and outcome of care, and populations requiring specialized care are a few of the issues that require more attention. Examples of relevant research topics include, but are not limited to:

- o Nature Or Type Of Home Care

A broad range of studies, (i.e., clinical, epidemiological, sociological, anthropological) are needed to examine the range of existing in-home health and supportive services. Specific examples include: the impact of new health care policies on the nature and type of community care options available (e.g., eligibility criteria for coverage); impact of high-tech clinical care in the home and its impact on the individual, caregivers, and/or the health care industry; the specific content of home care services (e.g., the duration, place and frequency of respite services and how these relate to caregiver use).

- o Use Of And Need For Home Care

Utilization of in-home health care and supportive services by older people and their families, the extent to which needs remain unmet, and the complex interactions between service need, service expectations, and service receipt are important areas for study. Others may include: epidemiological studies of the use of in-home health care and supportive services and changes in use over the course of an illness; development of criteria to measure "need for care" and examination of relationships between need and preferences; development of forecasting models to predict need for and use of in-home health care.

- o Process Of Home Care

How care is provided in the home and what structures are available to assist the older person, family, and/or other care providers are issues of continued importance. Research that examines different models of home care and/or links specific outcomes to particular interventions is needed. Still more information is needed on the process of care from the perspective of the client, the caregiver, or both. Areas that need further investigation are: alternative approaches to care (e.g., board and care) and structures for organizing care (e.g., shared-aide services); efforts to link care providers (e.g., board and care providers) with the larger community-based system; clinical intervention strategies designed to effectively impact health-related quality of life, functional status, and/or family relationships; transitions, such as initiation of informal or formal care services or transfer to and from nursing homes, and how they relate to the stage of caregiving and changing need for services.

- o Outcomes Of Home Care

An especially crucial aspect of in-home health care and supportive service research is defining and measuring quality. Therefore, research should focus on definitional and measurement issues related to quality as well as effectiveness for specific interventions being examined. Research may include: the effect of alternative approaches to in-home health care (e.g., personal assistance, respite care, high technology care or environmental modifications) on clients, family members, and other care providers as well as the development of more sensitive measures of stress, burden, satisfaction, and other outcomes; relevant outcomes of care,

especially those that lead to determination of effective forms of relief that could be offered to caregivers; strategies for increasing quality of life, health and/or socially related; and strategies to improve the functional status of clients; the cost and effectiveness of services, how services fit into the caregiver's living arrangements, and how services fit into the dynamics of kinship, friendship, and neighborhood networks.

o Special Care Populations

Many subpopulations are served by in-home health care and supportive services. To target services more effectively, the identification of care needs for specific subpopulations is necessary. Areas requiring additional study are: access to and utilization of care in special populations (e.g., the oldest old, women, minority and ethnic populations, rural elderly), and; the needs and resources of adults of all ages. Comparative research is encouraged on models of care for younger disabled ("independent living") populations and their relevance to care for older persons.

o Data Resources

Maximum use should be made of existing data. Primary data collection, however, may be necessary and certain types of databases have been highlighted as especially relevant. Both large-scale studies and smaller state, regional or local ones, as well as studies of board and care homes serving particular subgroups are appropriate. Moreover, it is important that studies capture the diversity of various forms of home care (e.g., large v. small, ownership, urban/suburban/rural) and the residents they serve (e.g., primarily private-pay v. SSI recipients, racial and ethnic subgroups). Studies may investigate: (a) the characteristics of the environment, (b) extent and characteristics of unmet care needs among residents, (c) relationships between different forms of in-home health care and the larger system, or (d) resident, owner/operator and staff "transitions". Attention should be given to specific forms of the home care industry that remain understudied, such as non-certified home health agencies, small, unlicensed board and care homes, and unlicensed social service providers.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If minorities and women are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and race/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority populations groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of minorities or women in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applicants are to use the research grant application form PHS 398 (rev. 9/91), available at the applicant's institutional Application Control Office and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 240, Bethesda, MD 20892, telephone (301) 496-7441. Complete item 2a on the face page of the application indicating that the application is in response to this announcement and print (next to the checked box) IN-HOME HEALTH AND SUPPORTIVE SERVICES.

The application (with five copies) must be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, or by the AHCPR. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applicants will compete for available funds with all other approved applications assigned to the Institute/Center/Division. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Marcia G. Ory
Behavioral and Social Research Program
National Institute on Aging
Gateway Building, Room 2C234
Bethesda, MD 20892
Telephone: (301) 496-3136

Dr. Patricia Moritz
Nursing Systems Branch
National Center for Nursing Research
Westwood Building, Room 754
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-0523

Ms. Anne Bavier or Ms. Linda Siegenthaler
Center for General Health Services Extramural Research
Agency for Health Care Policy and Research
Executive Office Center, Suite 502
2101 East Jefferson Street
Rockville, MD 20852-4908
Telephone: (301) 227-8357

Direct inquiries regarding fiscal matters to:

Ms. Linda Whipp
Grants and Contracts Management Office
National Institute on Aging
Gateway Building, Room 2N212
Bethesda, MD 20892
Telephone: (301) 496-1472

Sally A. Nichols
Grants Management Officer
National Center for Nursing Research
Westwood Building, Room 748
Bethesda, MD 20892
Telephone: (301) 496-0237

Ralph Sloat
Grants Management Officer
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 601
Rockville, MD 20852-4908
Telephone: (301) 227-8447

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.866, No. 93.336 (Nursing Research), No. 93.180, and 93.226. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and Title IX, as amended (Public Law 101-239), and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74 and 42 CFR 67, Subpart A. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

RESEARCH ON ANABOLIC STEROID ABUSE

NIH GUIDE, Volume 21, Number 18, May 15, 1992

PA: PA-92-80

P.T.34; K.W. 0404009, 0414014, 0710085, 0760085, 0411005, 1003008

National Institute on Drug Abuse
National Institute of Child Health and Human Development
National Institute of Diabetes and Digestive and Kidney Disease
National Cancer Institute
National Institute of Arthritis and Musculoskeletal and Skin Diseases

PURPOSE

The purpose of this announcement is to stimulate research and provide information to combat the misuse and abuse of anabolic steroids.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Research on Anabolic Steroid Abuse, is related to the priority area of alcohol and other drugs. The specific goal stated in "Healthy People 2000" is the reduction of anabolic steroid use among male high school seniors to three percent. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, (telephone 202- 783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, public or private, non-profit or profit-making organizations such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply. Foreign organizations are not eligible for the R29 award.

MECHANISMS OF SUPPORT

Support mechanisms include: Research Project (R01), small grant (R03), and First Independent Research Support and Transition (FIRST) Awards. Most investigator-initiated research are supported by research project grants. A research project grant is awarded to an institution on behalf of a Principal Investigator who has designed and will direct a specific project or set of projects. A research project grant can be renewed at intervals or supplemented through the formal submission and review process described below. An investigator may apply for a renewal (competing continuation) of an R01 grant by submitting an application for further support, including a report of progress and specific plans for future work. For information on the special requirements of the FIRST Award (R29) and the National Institute on Drug Abuse Small Grant (R03), contact the program staff listed at the end of this announcement.

RESEARCH OBJECTIVES

The widespread abuse of anabolic-androgenic steroids [derivatives of testosterone possessing both androgenic (virilizing) and anabolic (tissue building) properties, hereafter referred to as anabolic steroids] is a significant public health concern. Anabolic steroids are taken to enhance athletic performance and/or physical appearance. Of particular concern is the widespread use of anabolic steroids by adolescents.

In order to develop effective prevention efforts for anabolic steroid abuse, epidemiological and etiological studies are needed to characterize: the nature and extent of anabolic steroid use among the variety of sub-populations who use these drugs, the motivations for use by these subgroups, and the effectiveness of urine testing and other discouragement policies. Prevention efforts also are hampered by the lack of credible information on the consequences of anabolic steroid abuse. Data are needed on both short- and long-term health effects; psychological effects, including the possibility of dependence; and social consequences. In addition,

the use of injectable steroids raises the possibility of human immunodeficiency virus (HIV) transmission through needle-sharing. Therefore, data are needed on the prevalence of needle-sharing among the sub-populations of anabolic steroid users.

Examples of research topics relevant to this announcement include:

- o Studies to determine whether or not there are significant neuropsychiatric and psychosocial effects of anabolic steroid use. Examination of the profile of behavioral activity, elucidation of underlying neurobiological effects.
- o Studies to determine both the long-term sequelae and short-term biomedical effects of use and abuse of anabolic steroids in both male and female adolescents and adults. The occurrence and nature of these effects should be correlated with such factors as the particular steroid(s) used, doses and dosing regimens, and duration of steroid exposure. Areas of interest include effects on the hypothalamic-pituitary-gonadal axis, peri- and post-pubertal growth and body composition, effects on hepatic lipid metabolism and lipoproteins, cancer etiology studies examining cellular and molecular effects on the liver and other susceptible tissues.
- o Determination of the incidence and prevalence of anabolic steroid use in the general population and its determinants. Characterization of anabolic steroid users, e.g., socioeconomic status, race, educational level, and participation in competitive athletics.
- o Prevention research with focus on the following objectives: (1) measurement of the extent of the drug problem, (2) identification of salient psychosocial risk factors, and (3) development and testing of the efficacy of theory-based preventive interventions.
- o Improved techniques for analytical testing of anabolic steroids. Studies of how sports organizations integrate anabolic steroid testing into overall drug testing programs.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Sections 1-4 of the Research Plan AND summarized in Section 5 Human Subjects.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit. The receipt dates for applications for AIDS-related research are found in the PHS 398 instructions. The number and title of this announcement, "Research on Anabolic Steroid Abuse, PA-92-80," must be typed in item number 2a of the face page of the PHS 398 application form.

Application kits containing the necessary forms and instructions may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. These forms may also be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 240, Bethesda, MD 20892, telephone 301/496-7979.

The signed original and five permanent legible copies of the completed application must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary PHS grant programs. Applications received under this announcement will be assigned to an initial review group (IRG) in accordance with established Public Health Service Referral Guidelines. The IRG, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit. Notification of the initial review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by the appropriate National Advisory Council. Only applications recommended for further consideration by the Council may be funded.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to the Institute/Center/Division. The following will be considered when making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Direct inquiries regarding programmatic issues to:

Lynda Erinoff, Ph.D.
Neuroscience Research Branch
Division of Preclinical Research
National Institute on Drug Abuse
5600 Fishers Lane, Room 10A-19
Rockville, MD 20857
Telephone: (301) 443-6975

Gilman Grave, M.D.
Chief, Endocrinology, Nutrition and Growth Branch
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
Executive Plaza North, Room 637
Bethesda, MD 20892
Telephone: (301) 496-5593

Philip F. Smith, Ph.D.
Director, Endocrinology Research Program
Division of Diabetes, Endocrinology, and Metabolic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 621
Bethesda, MD 20892
Telephone: (301) 496-7341

Lea Sekely, Ph.D.
Chemical Carcinogenesis Branch
Division of Cancer Etiology
National Cancer Institute
Executive Plaza North, Room 700
Bethesda, MD 20892
Telephone: (301) 496-5471

Stephen Gordon, Ph.D.
Musculoskeletal Diseases Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
5333 Westbard Avenue, Room 407
Bethesda, MD 20892
Telephone: (301) 402-3338

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Direct inquiries regarding fiscal matters to:

Shirley Ann Denney
Chief, Grants Management Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 8A-54
Rockville, MD 20857
Telephone: (301) 443-6710

E. Douglas Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 501
Bethesda, MD 20892
Telephone: (301) 496-1303

Bruce Butrum
Grants Management Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 649
Bethesda, MD 20892
Telephone: (301) 496-7467

Jean Cahill
Team Leader, Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 47

Diane Watson
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
5333 Westbard Avenue, Room 403
Bethesda, MD 20892
Telephone: (301) 402-3352

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.279, 93.399, 93.849, 93.865, 93.846. Awards are made under authorization of the Public Health Service Act, sections 301 and 515 (42 USC 241 and 290cc) and administered under PHS grants policies and Federal Regulations 42 CFR 92 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

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Bethesda, MD 20816

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21., No. 19
May 22, 1992

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This publication is also available electronically to institutions via BITNET or INTERNET. Alternative access is through the NIH Grant Line using a personal computer. Contact Dr. John James at 301/496-7554 for details, or send an E-mail message to ZNS@NIHCU.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

NEUROSCIENCE RESEARCH ABOARD PROPOSED DECADE OF THE BRAIN NEUROLAB SPACE MISSION

NIH GUIDE, Volume 21, Number 19, May 22, 1992

Sources Sought: NIH-NINDS-92-001

P.T. 34; K.W. 1002030, 0710085, 0705070, 0414015, 0780015

National Institute of Neurological Disorders and Stroke

The National Aeronautics and Space Administration (NASA) and the National Institute of Neurological Disorders and Stroke (NINDS) seek information from individuals and organizations with the capability and interest in conducting basic and applied neuroscience research aboard the proposed Decade of the Brain Neurolab Space Mission, which is tentatively scheduled for early 1998. The Spacelab will provide access to the unique research environment of space flight for basic and applied studies. Where appropriate, ground-based studies will be supported to develop a protocol, collect data from related space experiments, test procedures, conduct simulations, and analyze flight data. Interested parties must submit five copies of a two-to-three-page summary of the proposed research, curricula vitae, and a concise and complete description of the organization's background.

Some scientific areas tentatively identified for emphasis include:

- o Developmental biology, including the role gravity plays in the development of motor control;
- o Cellular and molecular neurobiology, particularly as weightlessness would provide a tool to investigate the role gravity plays in intracellular and extracellular function and in cell-cell interaction;
- o Neural processing of sensory inputs at the cortical and subcortical levels and other functions of the nervous system that are particularly relevant to adaptation to gravity (balance, proprioception, motor control);
- o Behavior and performance including investigations using virtual reality and studies of crew interaction and human-machine interaction; and
- o Technology improvement and innovation: Investigators will be encouraged to incorporate the latest proven technology in the studies. New hardware will be designed so that it can later be deployed on Space Station Freedom for further research in the life sciences.

Neurolab will be configured as an integrated laboratory for neuroscience research, and it is anticipated that the following facilities will be available: cell culture facilities; animal housing for rats; glove box and work station for in-flight manipulation of the animals; biological sample processing and storage facilities; stimulating equipment for vestibular research; imaging equipment; electrophysiological equipment; facilities and equipment to sample blood and collect urine; laboratory computers and computer work stations; video; and virtual reality. Spacelab is a pressurized module that is contained in and attached to the cargo bay of the Space Shuttle. It has 22 cubic meters available for experiment hardware and equipment, is pressurized to 14.7 psi, and provides a "shirt sleeve" laboratory environment. The module contains utilities, work areas, and instrument racks for experiments.

Four crew members will be assigned to the science payload. By monitoring data and having air-to-ground dialogue and live TV from orbit, the investigators on the ground virtually work side-by-side with their colleagues in space.

The research can include experimental data collection before and after flight as well as during the flight. Experimental subjects will include the four science crew members; rats, ranging in age from neonatal to fully developed (aged); and invertebrates.

Since Neurolab is proposed to fly in 1998 and the project requires a long preparation, planning must start soon to meet that date.

This is not a Request for Proposals. It is a request for interest in participation. The government does not intend to make award on the basis of responses to this announcement nor to make payment for preparation of any information that may be submitted.

Responses must be submitted not later than July 3, 1992, to:

William Heetderks, M.D., Ph.D.
Division of Fundamental Neurosciences
National Institute of Neurological Disorders and Stroke
Federal Building, Room 916
Bethesda, MD 20892

RESEARCH ON MOLECULAR IMMUNOLOGY OF SEXUALLY TRANSMITTED DISEASES

NIH GUIDE, Volume 21, Number 19, May 22, 1992

RFA AVAILABLE: AI-92-09

P.T. 34; K.W. 0710070, 0715182, 1002008

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: August 7, 1992

Application Receipt Date: November 18, 1992

PURPOSE

The Sexually Transmitted Diseases Branch of the Division of Microbiology and Infectious Diseases (DMID) of the National Institute of Allergy and Infectious Diseases (NIAID) invites grant applications for program project grants to conduct basic research on the molecular nature of the human immune response to sexually transmitted diseases (STDs). The NIAID wishes to expand research in this area to develop molecular strategies to prevent infection, transmission, disease, and disease progression by immunization. Of particular interest is the integration of the disciplines of immunology and microbiology leading to productive interdisciplinary approaches that elucidate the basis of protective immunity to sexually transmitted infections.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Research on Molecular Immunology of STDs, is related to the priority area of sexually transmitted diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-10473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic non-profit and for-profit research institutions, public and private organizations such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Successful applicants funded under this RFA will be supported through a National Institutes of Health (NIH) program project grant (P01). This type of funding mechanism is utilized to encourage interdisciplinary investigator-initiated research, designed to elucidate various aspects or components of a central research objective, in areas of high priority to the NIAID. This RFA solicitation represents a single competition with a specified deadline for receipt of applications.

FUNDS AVAILABLE

The NIAID anticipates making two program project grant awards as a result of this RFA. The final number of awards to be made is dependent upon the availability of funds. The budget request for the initial year's total costs (direct and indirect) may not exceed \$1 million for each application. Applicants may request budgets of up to five years of support. Although the current NIAID policy is to limit the duration of program projects to four years, it is possible that the duration may be extended. The earliest possible award date is July 1993. Funding beyond the first and subsequent years of the award will be contingent upon satisfactory progress during the preceding years and upon availability of funds.

RESEARCH OBJECTIVES

A fundamental objective of the NIAID STD research program is to develop vaccines effective in preventing and controlling STDs. This requires focused interdisciplinary research to create effective molecular level strategies for eliciting protective immunity.

Research Scope

Research questions in areas of high priority include, but are not limited to, the following:

Molecular Specificity and Function of Immune Responses: What is the function of the immune response to infection? Does protective immunity occur as the result of infection? Since the surface of any given pathogen is a mosaic of antigens, and any given antigen is a mosaic of epitopes, it is essential to separate and characterize the specificity of protective and non-protective humoral and cellular immune responses occurring in sexually transmitted infections.

Immunity of the Reproductive Tract: How can protective immunity be induced in the reproductive tract? Given that protection against infection is absolutely dependent upon functional (i.e., protective), neutralizing antibodies at mucosal surfaces, the phenotype (including isotype), source, and specificity of these antibodies must be described. The role of CD4, CD8, and CD16 cells as well as other effector cells in protective immunity must be elucidated.

Can humoral and/or cellular immunity be induced that offers partial protection, i.e., reduces transmission, ameliorates disease or prevents disease progression?

What are the kinetic parameters of protective immune responses and how can protective immunity be enhanced both in terms of efficacy and longevity? It is necessary to characterize and compare protective immunity stimulated by direct inoculation of regional mucosal surfaces, other mucosal surfaces (e.g., oral), and parenteral routes. The role of cellular immunity in this process must be delineated.

What are the differences between the immune responses of the male and female reproductive tract? How do reproductive hormones influence infectivity and the host response to infection? What is the role of regional immunity in prevention or manifestation of sexually transmitted infections? Currently, little is known about the immunology of the female reproductive tract, and even less is known about the male reproductive tract. Does partial immunity play a role in asymptomatic disease, and if so, can this be correlated with the higher prevalence of silent infections in women compared to men?

SPECIAL REQUIREMENTS

Specific requirements and constraints for structuring Research on Molecular Immunology of Sexually Transmitted Diseases (ROMIS) program project applications are as follows:

Collaborative Interdisciplinary Approach: Each proposed project must combine microbiological and immunological approaches.

Central Focus on Human Immune Response: Minimally two, and preferably three, of the proposed projects must involve the study of some aspect of the human humoral or cellular immune response to sexually transmitted infections.

Clinical Facility and Study Population: All ROMIS program project applications must have a strong clinical facility with an accessible patient population appropriate to answering STD research questions. Characterization of the patients must include a microbiological evaluation of sexually transmitted infections, including, but not limited to, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Treponema pallidum*, human papillomavirus (HPV), herpes simplex virus (HSV), and human immunodeficiency virus (HIV).

Study Design: Study design must reflect epidemiological/biostatistical expertise including statistical power considerations and data analysis.

Required Number of Diseases or Syndromes: Research may be designed to focus on several STD pathogens or may focus entirely on a single STD pathogen. The number of pathogens proposed for study is less important than the quality of the science that is proposed within applications.

Diseases of Interest: Investigators are strongly encouraged to study the following diseases of interest: chlamydial infection, gonorrhea, HPV, syphilis, and genital herpes. HIV is not a pathogen of interest under this RFA unless the emphasis is on the role of the altered immune system on the course of the STD(s) under investigation.

Populations at Risk: Special emphasis should be placed on studying STDs in populations that are disproportionately affected by STDs and their sequelae: women, inner city minorities, adolescents, and infants.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations

for clinical studies, a special justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by August 7, 1992, a letter of intent that includes a descriptive title of the overall proposed research program and the name, address and telephone number of the Principal Investigator; the names of the proposed project leaders and other key personnel and participating institutions; and the number and title of the RFA in response to which the application may be submitted.

The letter of intent is to be sent to:

Dr. Olivia Preble
Scientific Review Board
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C-20
Bethesda, MD 20892
Telephone: (301) 496-8208

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these program project grant awards. These forms are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD, 20892, telephone 301-496-7441

REVIEW CONSIDERATIONS

Applications will be received by the Division of Research Grants. Applications will be reviewed by NIAID staff to determine administrative and programmatic responsiveness to this RFA; those judged to be non-responsive will be returned to the applicant without review.

Those applications considered responsive to the RFA may be subjected to a triage review by an NIAID peer review group, before or during the initial review committee meeting, to determine the scientific merit relative to the other applications submitted in response to the RFA. NIAID will withdraw from further competition those applications judged by the triage peer review group to be non-competitive for award, and will notify the Principal Investigator and institutional official.

Those applications judged to be responsive will be reviewed for scientific and technical merit by a review committee convened by the NIAID in March 1993. The second level of review will be provided by the National Advisory Allergy and Infectious Diseases Council in May 1993. The earliest award date is July 1993.

INQUIRIES

A copy of the RFA must be obtained before beginning the application process. Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA and inquiries regarding programmatic issues to:

Dr. Penelope J. Hitchcock
Acting Chief, Sexually Transmitted Diseases Branch
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3A-21
Bethesda, MD 20892
Telephone: (301) 402-0443

Direct inquiries regarding fiscal matters to:

Mr. Todd Ball
Grants Management Branch
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B-22
Bethesda, MD 20892
Telephone: (301) 496-7075

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.856, Microbiology and Infectious Disease Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

DEVELOPMENT OF A MODEL SYSTEM FOR IDENTIFYING NEONATAL HEARING IMPAIRMENT

NIH GUIDE, Volume 21, Number 19, May 22, 1992

RFA AVAILABLE: DC-92-06

P.T. 34; K.W. 0755020, 0715050, 0745020

National Institute on Deafness and Other Communication Disorders

Letter of Intent Receipt Date: July 31, 1992

Application Receipt Date: August 21, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The National Institute on Deafness and Other Communication Disorders (NIDCD) invites applications for assistance awards to support cooperative multi-center (consortium) studies of the sensitivity, specificity, and predictive efficiency of methods to identify neonatal (birth to three months) hearing impairment. The major purpose of this request is to increase, through consortium arrangements, the extent and depth of research leading to the development of timely and efficient methods of identification of neonatal hearing impairment.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Development of a Model System for Identifying Neonatal Hearing Impairment, is related to the priority area of maternal and infant health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-11474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-11473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Any of the following organizations are eligible to apply: foreign and domestic non-profit and for-profit organizations and institutions, state and local governments and their agencies, and authorized Federal agencies.

MECHANISM OF SUPPORT

The support mechanism for this consortium project will be a cooperative clinical research grant (R10). This RFA is a one-time solicitation. Funding in response to this RFA is dependent upon the receipt of applications of high scientific merit. The earliest start date for the initial awards will be April 1, 1993.

FUNDS AVAILABLE

Awards will be made for project periods of five years. Up to \$5 million total (direct plus indirect) costs is available for the entire project period of five years, or about \$1 million per year total for all awards. The NIDCD anticipates making one or two awards, but the specific amount and number of awards will depend on the merit and scope of the applications received. Budget increments after the first year will be limited to approved programmatic changes or to necessary cost-of-living increases. Although this project is provided for in the financial plans of the NIDCD, the award of grants pursuant to the RFA is contingent on the availability of funds appropriated for fiscal year 1993.

RESEARCH OBJECTIVES

The goal of this RFA is to support the conduct of coordinated multicenter studies (consortium arrangements), leading to the development of a system for identification of neonatal hearing impairment. Areas of research appropriate to the RFA may include, but are not limited to: screening normal and at-risk neonates with both auditory brainstem response (ABR) and otoacoustic emission (OAE) recordings; determining optimum stimulus and recording parameters for OAE; assessing the influence of co-existing medical factors on characteristics of ABR and OAE; assessing development related changes in OAEs that may occur particularly during the first year; establishing monaural threshold sensitivity for pure tones and speech; evaluating sensitivity, specificity, and predictive efficiency of ABR and OAE test methods, singly and in combination; and evaluation of time and cost-efficiency of the procedures. The goals of this RFA can be met by including the above areas of research in an application encompassing three project phases: screening, follow-up, and data analysis. A pilot or start-up phase of up to four months may also be included. Emphasis should be placed on the existing and potential strengths of the applicant organization related to the fulfillment and completion of the objectives of this RFA. Appropriate areas should include, but are not limited to: arrangements for biostatistical and/or epidemiologic support, collaborations for ensuring availability of patients, arrangements for patient accrual, arrangements for coordination among cooperating institutions, identification of essential personnel for recruitment, and development of plans for acquiring or providing any special research skills needed.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 31, 1992, a letter of intent that includes a descriptive title of the proposed project, the name and address of the Principal Investigator, the names of other key personnel and collaborating institutions, and the number and title of the RFA in response to which the application is being submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, submission of such a document allows NIDCD review staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Amy Donahue, Ph.D.
Chief, Hearing Program
Division of Communication Sciences and Disorders
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Suite 400B
6120 Executive Boulevard
Rockville, MD 20892
Telephone: (301) 402-3458
FAX: (301) 402-6251

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91) using the instructions included in the application kit. These kits are available from most institutional offices of sponsored research, the NIDCD Program Administrator cited below, and the Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441. On page 1 of form PHS 398, check "yes" in item 2a and type: RFA DC-92-01: Development of a Model System for the Identification of Neonatal Hearing Impairment.

Complete applications are due no later than August 21, 1992, and must address all requirements in the RFA.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator must be included with the application.

REVIEW CONSIDERATIONS

Applications will be evaluated by NIDCD program staff to determine responsiveness to the RFA. Responsive applications will then be evaluated for scientific and technical merit by a review committee convened by the Scientific Review Branch of the NIDCD solely for this purpose. A second level review will be conducted by the National Deafness and Other Communication Disorders Advisory Council. Applications that are judged non-responsive will be administratively withdrawn, and the proposed Principal Investigator and institutional business official will be notified. Should an application be judged non-responsive to this RFA, any of its constituent projects may be submitted as an investigator-initiated individual research grant (R01) at the next receipt date or later. The new application would not be considered a response to an RFA.

Factors considered to be important for review include demonstrated expertise in pediatric audiology, identification audiometry, neonatology, biostatistics and physiologic methods of hearing assessment; documentation of availability of an appropriate patient population; documented plans for interaction among collaborating institutions and clinicians; administrative support by the hospitals, clinics, or medical centers for all phases of the studies; and adequate facilities and ancillary personnel.

Reviewers will review the grant applications by considering the following criteria:

- o Appropriateness, originality, feasibility, and relevance of the proposed project to the overall goals and objectives of the RFA.
- o Qualifications, experience and proposed responsibilities of the Principal Investigators and key personnel.
- o Scientific merit and organizational plans for implementing the proposed program.
- o Demonstration of availability of normal and at-risk patient populations.
- o Proposed collaborations among audiologists, otolaryngologists, neonatologists, nursing staff, and other key personnel within the applicant and collaborating institutions; adequacy of documented interest, capabilities, and commitment of all potential participating clinics.



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- o Facilities and resources, and the availability of such for this project.
- o Adequacy of proposed overall administrative procedures and inter- and intra-institutional collaborative arrangements.
- o Reasonableness and appropriate justification of the proposed budget.
- o Plans to protect the rights and welfare of human subjects, including appropriate informed consent procedures.

AWARD CRITERIA

The anticipated date of award is April 1, 1993.

In addition to technical merit, award decisions will be based on the responsiveness to RFA, the availability of resources, and the adequacy of the study populations.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Direct inquiries regarding programmatic issues to:

Amy Donahue, Ph.D.
Chief, Hearing Program
Division of Communication Sciences and Disorders
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Suite 400-B
6120 Executive Boulevard
Rockville, MD 20852
Telephone: (301) 496-5061
FAX: (301) 402-6251

Direct inquiries regarding fiscal matters and explanation of the requirements for the formation of consortia to:

Sharon Hunt
Division of Extramural Activities
Grants Management Branch
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Suite 400-B
6120 Executive Boulevard
Rockville, MD 20852
Telephone: (301) 402-0909

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.173. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

5333 Westbard Avenue
Bethesda, MD 20816

NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 21., No. 20

May 29, 1992

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This publication is also available electronically to institutions via BITNET or INTERNET. Alternative access is through the NIH Grant Line using a personal computer. Contact Dr. John James at 301/496-7554 for details, or send an E-mail message to ZNS@NIHCU.

NOTICES OF AVAILABILITY (RFPS AND RFAs)BRAIN AND TISSUE BANK FOR DEVELOPMENTAL DISORDERS

NIH GUIDE, Volume 21, Number 20, May 29, 1992

RFP AVAILABLE: RFP NICHD-CRMC-92-19

P.T. 34; K.W. 0780000, 0780020, 0705010, 0715130, 0720010, 0715205

National Institute of Child Health and Human Development

The National Institute of Child Health and Human Development (NICHD) is planning to establish an additional repository to collect, store, and distribute specimens from infants and children with neurodevelopmental disorders both from "unaffected" (control) individuals and from individuals with developmental disorders. The biopsy and/or autopsied tissues to be included in the brain and tissue bank would encompass the following disorders: diagnosed Down's syndrome, other chromosome defects, mitochondrial encephalopathies, phenylketonuria and other aminoacidopathies, maternal phenylketonuria, Rett syndrome, leukodystrophies, lysosomal disorders, unexplained forms of mental retardation, sudden infant death syndrome (SIDS), dyslexia, autism, and other neurodevelopmental disorders. Specific tissues to be collected will include the following: brain, spinal cord, cerebrospinal fluid, blood and serum, peripheral nerves, liver, kidney, pancreas, lungs, spleen, adrenal, skeletal muscles, heart, skin, thyroid, lymph nodes, and gonads. Tissues would be obtained premortem, postmortem, and from abortions. These tissues will be made available to qualified investigators to support and facilitate research that will lead to an improved understanding of the etiology, pathology, pathogenesis, and clinical-pathological correlation of conditions that are associated with mental retardation, learning and behavioral deficits, and SIDS.

This announcement for a brain and tissue bank is a new solicitation that will be performed in collaboration with an existing procurement (N01-HD-1-3138--University of Maryland, Baltimore). The Project Officers will create a steering committee to foster this collaboration. The offeror shall not arrange the joint endeavor.

The issuance of this Request for Proposals (RFP) will be on or about June 1, 1992 and proposals are due by 4:00 p.m. (Local Time), August 3, 1992. Those organizations desiring a copy of the above RFP may send a written request to Mrs. Lynn Salo at the address listed below. All requests must cite the RFP number above and include

two self-addressed mailing labels. All sources who consider themselves qualified are encouraged to submit a proposal. This advertisement does not commit the Government to award a contract.

Mrs. Lynn Salo
Contract Specialist
National Institute of Child Health and Human Development
Office of Grant and Contracts
Contract Management Branch
6100 Executive Boulevard, Room 7A07R
Rockville, MD 20852
Telephone: (301) 496-4611

INTERNATIONAL TRAINING GRANTS IN EPIDEMIOLOGY RELATED TO THE ACQUIRED IMMUNODEFICIENCY SYNDROME

NIH GUIDE, Volume 21, Number 19, May 22, 1992

RFA AVAILABLE: TW-92-02

P.T. 44; K.W. 0720005, 0715008, 0785055

Fogarty International Center

Letter of Intent Receipt Date: July 1, 1992
Application Receipt Date: September 10, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACTS NAMED IN "INQUIRIES" BELOW.

PURPOSE

The Fogarty International Center (FIC), National Institutes of Health (NIH), invites applications to develop international training programs in epidemiology related to Acquired Immunodeficiency Syndrome (AIDS) for foreign health scientists, clinicians, and allied health workers. This announcement is for the second five-year funding cycle. Both new and competing renewal applications for this program are welcome.

A major goal of the program is to train scientists of other countries to deal effectively with the AIDS epidemic through epidemiologic research, clinical trials, and AIDS prevention research programs.

In February 1992, the FIC completed a comprehensive review of the program. The basic rationale for the program was reaffirmed. A number of useful recommendations were made, and the most relevant are incorporated into this announcement.

Major changes for the second five-year funding cycle include a shift in emphasis from short- to long-term training and greater emphasis on advanced research training in-country. Applicants are encouraged to develop training programs that facilitate the conduct of future international vaccine and drug trials in an ethical and equitable manner. This program will continue to emphasize trainees from, and training activities in, the developing countries of Africa, Latin America and the Caribbean, and Asia and the Pacific region. The program will also accommodate trainees from, and training activities in, countries of Central and Eastern Europe and the former Soviet Union.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, International Training Grants In Epidemiology Related To AIDS, is related to the priority area of HIV infections. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-0473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Eligible institutions must be a U.S., non-profit, private or public institution capable of meeting the objectives described in this RFA. Only one application will be allowed under this program from each U.S. institution.

MECHANISM OF SUPPORT

Grants will be made as international training grants in epidemiology (D43) for a total project period of five years. Continued support depends on satisfactory performance as judged by annual progress reports, during site visits, and meetings of program directors.

FUNDS AVAILABLE

Approximately \$4,000,000 (total costs) will be allocated to this program in FY 1993, availability of funds permitting, resulting in an estimated ten awards, depending upon the quality of applications. The total (direct and indirect) cost per grant for the first year may not exceed \$600,000 for competing continuation applications and \$400,000 for new programs.

RESEARCH OBJECTIVES

The objectives are to train scientists, particularly from developing countries, to deal effectively with the AIDS epidemic through epidemiologic research, clinical trials, and AIDS prevention research. The program is intended to support collaborative research between U.S. and foreign scientists to enhance knowledge and skills in the epidemiology, diagnosis, and treatment of Human Immunodeficiency Virus (HIV)/AIDS and to stimulate scientists from nations affected by AIDS to cooperate and share knowledge in combatting this global problem.

Emphasis will be on developing human resources in developing countries likely to be hosts of HIV/AIDS-related research and field trials of anti-HIV drugs, HIV vaccines, and other interventions.

Specifically, the program is designed to:

- o Increase expertise in epidemiology and laboratory components of AIDS-related epidemiologic research through short- and long-term training at U.S. institutions that may lead to M.S. and/or Ph.D. degrees in epidemiology;
- o Increase laboratory expertise of technical assistants in foreign countries who are engaged in epidemiological studies related to HIV/AIDS through in-country, short-term, didactical, and technical training; and
- o Expand ongoing collaborative training and research in HIV/AIDS between U.S. and foreign scientists.

Trainees shall be individuals involved in or expected to be involved in epidemiological research related to AIDS and AIDS prevention research activities in their home country. The following categories of individuals are eligible:

- o Foreign health professionals (M.D., Ph.D., equivalent);
- o Foreigners with a bachelors or masters degree in a basic or health science;
- o Technicians and health care workers;
- o Allied health professionals such as nurses and social workers; and
- o Current or former trainees involved in advanced research training in their home countries.

The program's focus must be on HIV/AIDS and opportunistic infections and diseases strongly associated with AIDS (e.g., sexually transmitted diseases (STDs) and tuberculosis).

SPECIAL REQUIREMENTS

Applicants are required to describe training in responsible conduct of research to be part of the programs. An award will not be made unless such a description is included.

Before any funds can be expended from this award, the grantee institution must show evidence of approval for collaborative research between the U.S. and foreign countries and institutions included in the program through an endorsement from the Minister of Health or other appropriate government official and from the collaborating institutions.

STUDY POPULATIONS

While the majority of support for training-related research may be derived from sources other than this award, prospective awardees are expected to comply with NIH policy concerning study populations.

LETTER OF INTENT

Prospective applicants are requested to submit a letter of intent, by July 1, 1992, that includes the number and title of this RFA, names of the program director and other key participating faculty, if known, and the identity of the U.S. and foreign countries and institutions involved.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is helpful in planning for review of applications, allows estimates of potential review workload and avoids conflict of interest in the review.

The letter of intent is to be sent to:

Dr. Sherry Dupere
Scientific Review Administrator
Fogarty International Center
National Institutes of Health
Building 31, Room B2C32
Bethesda, MD 20892
FAX: (301) 402-2056

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for this grant. These forms are available at most U.S. institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda MD 20892 (telephone 301-496-7441).

Applications must be received by September 10, 1992. Applications received after that date will be returned to the applicant.

REVIEW CONSIDERATIONS

Applications will be reviewed to determine completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, it also will be returned to the applicant.

Those applications that are complete and responsive may be subjected to triage by an FIC peer review group to determine scientific merit relative to the other applications received. The NIH reserves the right to withdraw from competition those applications judged as non-competitive.

Those applications judged to be competitive for award will be further reviewed for scientific and technical merit by the Review Committee convened by the FIC during November 1992. The committee will conduct a scientific evaluation of each application and determine the likelihood that the applicant institution can meet the objectives of the program considering the factors stated in this RFA. The final review will be provided by the FIC Advisory Board in February 1993. The Director, FIC, will make the final funding decisions.

The anticipated date of award is September 1993.

INQUIRIES

Prospective applicants are strongly encouraged to discuss their applications, including proposed collaborating countries and institutions, with FIC program staff (see below) before submitting formal applications. It is essential that prospective applicants receive a copy of the RFA before developing an application.

Programmatic and scientific inquiries may be directed to:

Dr. Kenneth Bridbord
Chief, International Studies Branch
Fogarty International Center
National Institutes of Health
Building 31, Room B2C32
Bethesda, MD 20892
Telephone: (301) 496-2516

Inquiries related to the review of these applications may be directed to:

Dr. Sherry Dupere
Scientific Review Administrator
Fogarty International Center
National Institutes of Health
Building 31, Room B2C32
Bethesda, MD 20892
Telephone: (301) 496-2516

AUTHORITY AND REGULATIONS

Awards under this program are made under the authority of the Public Health Service Act, Section 307 (42 USC 2421) and administered under PHS grants policies and Federal regulations, most specifically 42 CFR part 61. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to Health Systems Agency review.

SPECIAL INTERNATIONAL POSTDOCTORAL RESEARCH PROGRAM IN ACQUIRED IMMUNODEFICIENCY SYNDROME

NIH GUIDE, Volume 21, Number 19, May 22, 1992

RFA AVAILABLE: TW-92-03

P.T. 44; K.W. 0720005, 0715008, 0785055, 0745020, 0745027, 0745070

Fogarty International Center

Letter of Intent Receipt Date: July 1, 1992
Application Receipt Date: September 10, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACTS NAMED IN "INQUIRIES" BELOW.

PURPOSE

The Fogarty International Center (FIC) invites applications to develop multi-disciplinary postdoctoral fellowship programs in Acquired Immunodeficiency Syndrome (AIDS) research for foreign and U.S. scientists. International cooperation is important in understanding and preventing human immunodeficiency virus (HIV) infection/AIDS. Funds will be awarded to encourage basic and population-based research in all biomedical and behavioral disciplines related to AIDS. This announcement is for the second five-year funding cycle for this program. Both new and competing applications for this T22 program are welcome.

In February 1992, the FIC completed a comprehensive review of the program. The basic rationale for the program was reaffirmed. A number of useful recommendations were made and the most relevant incorporated into this announcement.

Major changes for the second five-year funding cycle include a shift in emphasis from short- to long-term training and greater emphasis on advanced research training in-country. Applicants are encouraged to develop training programs that facilitate the conduct of future international vaccine and drug trials in an ethical and equitable manner. This program will continue to emphasize trainees from, and training activities in, the developing countries of Africa, Latin America and the Caribbean, and Asia and the Pacific region. The program will also accommodate trainees from, and training activities in, countries of Central and Eastern Europe and the former Soviet Union.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Special International Postdoctoral Research Program In Acquired Immunodeficiency Syndrome (AIDS), is related to the priority area of HIV infections. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-0473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Eligible institutions must be a U.S., non-profit, private or public institution capable of meeting the objectives in the RFA. Only one application will be allowed under this program from each U.S. institution.

MECHANISM OF SUPPORT

Grants will be made as institutional research fellowship (T22) awards for a total project period of five years. Continued support depends on satisfactory performance as judged by annual progress reports and during site visits and meetings of program directors.

FUNDS AVAILABLE

Approximately \$1,000,000 (total costs) will be allocated to this program in FY 1993, availability of funds permitting, resulting in an estimated four awards, depending upon the quality of applications. The total (direct and indirect) cost per grant for the first year may not exceed \$300,000 for continuing and \$200,000 for new programs.

RESEARCH OBJECTIVES

The objectives are (1) to support collaborative research between U.S. and foreign scientists who wish to enhance their knowledge and skills in the epidemiology, diagnosis, prevention, and treatment of HIV/AIDS and (2) to stimulate scientists from nations affected by AIDS to cooperate and to share research knowledge in combatting this global problem.

Under this award the program director will make the following types of training appointments to foreign and U.S. scientists:

- o Postdoctoral research training conducted at U.S. institutions for foreign scientists varying from 3-24 months in duration. Postdoctoral scientists (e.g., M.D.s, Ph.D.s) at all career levels are eligible for appointment. Training includes basic and clinical research in all biomedical and behavioral disciplines related to HIV/AIDS and is meant to enhance knowledge and skills in the epidemiology, diagnosis, prevention, and treatment of HIV/AIDS.
- o Postdoctoral research training conducted at foreign institutions for U.S. scientists varying from 3-24 months duration. Scientists at all postdoctoral career levels are eligible for appointment to this type of training.
- o Advanced in-country research training conducted at foreign institutions for selected, highly qualified foreign scientists under guidance of participating U.S. faculty, varying from 3-24 months duration.

The program's focus should be on HIV/AIDS and opportunistic infections and diseases strongly associated with AIDS (e.g., sexually transmitted diseases (STDs) and tuberculosis). Emphasis will be on developing human resources in developing countries likely to be hosts for HIV/AIDS-related research and field trials of anti-HIV drugs, HIV vaccines, and other interventions.

SPECIAL REQUIREMENTS

Applicants are required to describe training in responsible conduct of research to be part of the programs. An award will not be made unless such a description is included.

Before any funds can be expended from this award, the grantee institution must show evidence of approval for collaborative research between the U.S. and foreign institutions and/or from the foreign government through an endorsement from the Ministry of Health or other appropriate government official.

STUDY POPULATIONS

While the majority of support for training-related research may be derived from sources other than this award, prospective awardees are expected to comply with NIH policy concerning study populations.

LETTER OF INTENT

Prospective applicants are requested to submit a letter of intent, by July 1, 1992, that includes the number and title of this RFA, names of the program director and other key participating faculty, if known; and the

identity of the U.S. and foreign countries and institutions involved.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is helpful in planning for the review of applications, allows estimates of potential review workload and avoids conflict of interest in the review.

The letter of intent is to be sent to:

Dr. Sherry Dupere
Scientific Review Administrator
Fogarty International Center
National Institutes of Health
Building 31, Room B2C32
Bethesda, MD 20892
FAX: (301) 402-2056

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for this grant. These forms are available at most U.S. institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda MD 20892 (telephone 301-496-7441).

Applications must be received by September 10, 1992. Applications received after that date will be returned to the applicant.

REVIEW CONSIDERATIONS

Applications will be reviewed to determine completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, it also will be returned to the applicant.

Those applications that are complete and responsive may be subjected to triage by an FIC peer review group to determine scientific merit relative to the other applications received. The NIH reserves the right to withdraw from competition those applications judged as non-competitive.

Those applications judged to be competitive for award will be further reviewed for scientific and technical merit by the Review Committee convened by the FIC during November 1992. The committee will conduct a scientific evaluation of each application and determine the likelihood that the applicant institution can meet the objectives of the program considering the factors stated in this RFA. The final review will be provided by the FIC Advisory Board in February 1993. The Director, FIC, will make the final funding decisions.

The anticipated date of award is on or about July 1, 1993.

INQUIRIES

Prospective applicants are strongly encouraged to discuss their applications, including proposed collaborating countries and institutions, with FIC program staff (see below) before submitting formal applications. It is essential that prospective applicants receive a copy of the RFA from the FIC before developing an application.

Programmatic and scientific inquiries may be directed to:

Dr. Kenneth Bridbord
Chief, International Studies Branch
Fogarty International Center
National Institutes of Health
Building 31, Room B2C32
Bethesda, MD 20892
Telephone: (301) 496-2516

Inquiries related to the review of these applications may be directed to:

Dr. Sherry Dupere
Scientific Review Administrator
Fogarty International Center
National Institutes of Health
Building 31, Room B2C32
Bethesda, MD 20892
Telephone: (301) 496-2516

AUTHORITY AND REGULATIONS

This program of the John E. Fogarty International Center for Advanced Study in the Health Sciences is identified in the Catalog of Federal Domestic Assistance, No. 93.154. Awards will be made under the authority of the Public Health Service Act, Section 307 (42 USC 2421) and administered under PHS grants policies and Federal regulations, most specifically 42 CFR part 61. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to Health Systems Agency review.

COMMUNITY CLINICAL ONCOLOGY PROGRAM

NIH GUIDE, Volume 21, Number 20, May 29, 1992

RFA AVAILABLE: CA-92-15

P.T. 34; K.W. 0785035, 0785035, 0785140, 0403004, 0795003

National Cancer Institute

Letter of Intent Receipt Date: June 29, 1992

Application Receipt Date: August 24, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES BELOW.

PURPOSE

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications for cooperative agreements to the Community Clinical Oncology Program (CCOP). New community and research-base applicants and currently funded programs are invited to respond to this RFA.

This issuance of the CCOP RFA seeks to build on the strength and demonstrated success of the CCOP over the past nine years by continuing the program as a vehicle for supporting community participation in cancer treatment and cancer prevention and control clinical trials through research bases (clinical cooperative groups and cancer centers supported by NCI) and utilizing the CCOP network for conducting NCI-assisted cancer prevention and control research.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Community Clinical Oncology Program, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

New applicants and currently funded programs are eligible as described below. Two categories of awards will be made: community programs and research bases. A community applicant may be a hospital, a clinic, a group of practicing physicians, a health maintenance organization (HMO), or a consortium of these. Community programs will be required to enter patients onto NCI-approved treatment and cancer prevention and control clinical trials through the research base(s) with which each CCOP is affiliated.

Research-base applicants must be either an NCI-funded clinical trials cooperative group or a cancer center. Research bases will be required to provide clinical research treatment and cancer prevention and control protocols, monitor the quality of the research, and follow CCOP accrual.

MECHANISM OF SUPPORT

Support of this program will be through the cooperative agreement (U01), an assistance mechanism in which substantial NCI programmatic involvement with the recipients during performance of the planned activity is anticipated, to assist awardees in the planning, direction, and execution of the proposed project. The total project period for applications submitted in response to this RFA may not exceed three years for new applicants and five years for applicants currently supported under this program. Currently supported applicants will be funded for three, four, or five years depending upon priority score/percentile, review committee recommendations, and programmatic considerations.

FUNDS AVAILABLE

It is anticipated that up to \$2.5 million in total costs per year for five years will be committed to specifically fund applications submitted in response to this RFA. Of the total, approximately \$300,000 will be committed to research bases and approximately \$2.2 million to CCOPs. It is anticipated that up to 3 research base awards and up to 16 CCOP awards will be made. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

Background

Over 80 percent of patients with cancer are treated in the community. The CCOP was initiated in 1983 to bring the benefits of clinical research to cancer patients in their own communities by providing support for physicians to enter patients onto treatment research protocols. The second RFA, issued in 1986, expanded the focus to include cancer prevention and control research. In 1991, there were 52 programs in 27 states involving more than 300 hospitals and 2,600 physicians. Approximately 5,000 patients were entered onto treatment trials and 4,000 subjects per year onto cancer prevention and control studies.

Cancer prevention and control research in the CCOPs is aimed at reducing cancer incidence, morbidity, and mortality through the identification, testing, and evaluation of interventions in controlled clinical trials. The 80 protocols activated to date cover the full spectrum of cancer prevention and control research, including chemoprevention and marker studies for future prevention interventions, smoking cessation studies, screening and early detection, and pain control and other symptom management interventions.

Goals and Scope

The CCOP initiative is designed to bring the advantages of state-of-the-art treatment and cancer prevention and control research to individuals in their own communities by having practicing physicians and their patients/subjects participate in NCI-approved treatment and cancer prevention and control clinical trials. The CCOP also provides a mechanism to increase the involvement of primary health care providers and other health care specialists in treatment and cancer prevention and control research and provides an opportunity for education and exchange of information on new technologies.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit by June 29, 1992, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NCI staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

Letters of intent are to be sent to:

Leslie G. Ford, M.D.
Chief, Community Oncology and Rehabilitation Branch
National Cancer Institute
Executive Plaza North, Room 300-D
Bethesda, MD 20892
Telephone: (301) 496-8541

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for cooperative agreements. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301-496-7441; and the NCI program official named in the LETTER OF INTENT.

All applicants are strongly encouraged to obtain and use the suggested application format instructions from the program official named in the section, LETTER OF INTENT. A suggested format will be sent to applicants submitting a letter of intent.

Applications must be received by August 24, 1992. If an application is received after that date, it will be returned to the applicant.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the Division of Research Grants for completeness and by NCI staff for responsiveness. Incomplete and non-responsive applications will be returned to the applicant without further consideration. Applications will be triaged by an NCI peer review group on the basis of relative competitiveness. The NCI will withdraw from further competition those applications judged to be non-competitive for award and notify the applicant Principal Investigator and institutional official. Those applications judged to be competitive will undergo further scientific merit review in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NCI. The second level of review will be provided by the National Cancer Advisory Board.

Review Criteria

Review criteria for CCOP applicants include the ability to accrue a minimum of 50 credits per year to cancer prevention and control clinical trials and at least 50 credits to cancer treatment clinical trials. Review criteria for Research Bases include the ability to design appropriate treatment and/or prevention and control clinical trials. For both CCOP's and Research Bases the qualifications and experience of personnel and the stability and past performances of the functional unit applying will also be considered. The review group will critically examine submitted budgets and recommend an appropriate budget and period of support.

AWARD CRITERIA

The anticipated date of award is June 1, 1993. NCI program staff will take into account demographic and geographic distribution of applicants in the final funding selection process to ensure inclusion of minority and underserved populations. If more than one CCOP applicant competes for the same patient population, all may not be awarded unless warranted by the population density.

INQUIRIES

Written and telephone requests for the RFA, inquiries concerning the objectives and scope of this RFA, and whether or not specific proposed research is responsive are encouraged and should be directed to Dr. Ford, at the address provided in the LETTER OF INTENT.

Direct inquiries regarding fiscal matters to:

Ms. Crystal Elliott
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892.
Telephone (301) 496-7800, ext. 19

AUTHORITY AND REGULATION

This program is described in the Catalog of Federal Domestic Assistance No. 93.399, Cancer Control. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410 as amended by Public Law 99- 158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems review.

ALCOHOL RESEARCH CENTER GRANTS

NIH GUIDE, Volume 21, Number 20, May 29, 1992

RFA AVAILABLE: AA-92-03

P.T. 34; K.W. 0404003, 0755030, 0745020, 0745027, 0795003, 0415001

National Institute on Alcohol Abuse and Alcoholism

Application Receipt Date: December 10, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) provides grant support for Alcohol Research Centers to conduct interdisciplinary research on alcoholism and alcohol abuse. The center grants program is interrelated with and complementary to all other research support mechanisms and scientific activities that comprise the NIAAA programs of research on the nature, causes, diagnosis, treatment, control, prevention, and consequences of alcohol abuse and alcoholism.

A center is expected to be a source of scientific excellence and, through sustained excellence, to become a significant regional or national research resource. In addition, the applicant institution is expected to afford opportunities for research training to persons from various disciplines and professions.

Support from the initial five-year grant awards for two of the existing centers will expire on November 30, 1993. Research within each of these two centers is organized around a central theme, respectively, alcohol and aging, and alcohol and immunology including AIDS/HIV infection. It is the intent of the NIAAA to continue to support a center that addresses research questions of alcohol and aging. It is also the intent of the NIAAA to continue to support a center that addresses research issues on alcohol and immunology, although other themes may be considered. Applications for new centers will be evaluated with applications from currently funded centers seeking renewal support beyond November 30, 1993.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Alcohol Research Center Grants, is related to the priority area of alcohol abuse and alcoholism reduction. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone: 202-783-3238.

ELIGIBILITY REQUIREMENTS

Any domestic, public (non-Federal) or private, non-profit or for-profit institution may apply for a center grant. However, the proposed center must be affiliated with an institution, such as a university, medical center, or research center, that has the resources to sustain a long-term coordinated research program. An

applicant institution must demonstrate the ability to attract high-quality scientists from biomedical, behavioral, and/or social science disciplines who are willing to make a long-term commitment to research. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

A Specialized Center Grant (P50) is a comprehensive, broad-based multidisciplinary, multi-investigator, long-term program of combined research and research support activity planned around a specific major research objective or research theme. In addition to providing support for shared resources, this type of center supports a full range of basic, developmental, clinical, and/or applied research components; allows for growth and development through pilot projects; and is intended to provide state-of-the-art leadership in the alcohol field.

FUNDS AVAILABLE

It is estimated that approximately \$3-4 million will be available in FY 1994 to fund approximately two centers.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN RESEARCH

For projects involving clinical research, ADAMHA requires applicants to give special attention to the inclusion of women and minorities in study populations. If women and minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit by October 1, 1992, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIAAA staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

Letter of intent are to sent to Dr. Ernestine Vanderveen at the address provided in INQUIRIES.

APPLICATION PROCEDURES

Applicants are to use the grant application form PHS 398 (rev. 9/91). The title and number of this RFA, Alcohol Research Center Grants, AA-92-03, must be typed in item number 2a on the face page of the PHS 398 application form.

REVIEW PROCEDURES

Each center application will be reviewed by a group of experts convened by the NIAAA to evaluate the scientific and technical merit of the application. Recommendations from this review will be presented to the National Advisory Council on Alcohol Abuse and Alcoholism that will make a final recommendation to the Director, NIAAA.

INQUIRIES

For a copy of the RFA and preapplication consultation contact:

Dr. Ernestine Vanderveen
Associate Director, Division of Basic Research
National Institute on Alcohol Abuse and Alcoholism
5600 Fishers Lane, Room 16C-06
Rockville, MD 20857
Telephone: (301) 443-1273

Direct inquiries relating to fiscal matters to:

Edward Ellis,
Grants Management Specialist
Grants Management Branch
National Institute on Alcohol Abuse and Alcoholism
5600 Fishers Lane, Room 16-86
Rockville, MD 20857
Telephone: (301) 443-4703

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.891. The statutory authorities for awards under this RFA are Sections 301 and 511 of the Public Health Service Act (42 USC 241 and 290bb-1). Federal Regulations at 42 CFR Part 54a, Subpart E "Grants for National Alcohol Research Centers" apply to grants under this RFA. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SURGICAL ONCOLOGY

NIH GUIDE, Volume 21, Number 20, May 29, 1992

PA NUMBER: PA-92-81

P.T. 34; K.W. 0715035, 0785140, 0785210

National Cancer Institute

PURPOSE

The Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI) is seeking applications for investigator-initiated research grants concerned with research in surgical oncology. The Principal Investigator must be a surgeon. This Program Announcement (PA) is designed to promote and develop a strong cadre of academic surgeons involved in clinical research. A PA is used to stimulate investigator-initiated research projects in areas of special interest to the National Cancer Program.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Surgical Oncology, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged. Applications from one or more institutions (individual institutions, consortia, cancer centers) with established clinical, laboratory, and statistical resources are solicited. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) Award. The special eligibility criteria for the FIRST Award (R29) can be found in the Guidelines for FIRST AWARD (version February 1991). The Guidelines for FIRST AWARD can be obtained from the Grants Inquiries Office, Division of Research Grants, NIH (301-496-7441).

MECHANISM OF SUPPORT

Awards will be made as FIRST awards (R29s), research project grants (R01s) and interactive R01s in accordance with Public Health Service (PHS) policies applicable to research project grants. A description of an interactive R01 application can be found in the NIH Guide for Grants and Contracts (Vol. 21, No. 1, January 10, 1992) under PA-92-29. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 90-50,000, revised October 1, 1990.

RESEARCH OBJECTIVES

Summary

The treatment of cancer has evolved as multi-disciplinary effort involving, but not limited to, the disciplines of surgical oncology, medical oncology, pediatric oncology, and radiation oncology. The disciplines of medical oncology, pediatric oncology, and radiation oncology have developed strong cadres of academic investigators while academic development in surgical oncology has not kept pace. It is felt that surgical oncology is not keeping pace because of an insufficient number of surgical oncology research programs and an insufficient number of surgeons undertaking research related to cancer. Continued development of superior multi-disciplinary treatment of cancer is the long-range objective of the DCT and the attainment of the goal requires sufficient academic strength in investigative surgical oncology.

Examples of relevant studies include mechanisms of metastases, effect of surgery on tumor cell kinetics, and tumor host responses to surgery. Preclinical and clinical research is encompassed in this program. Categories of research include but, are not confined to, the following: (1) pathophysiologic studies in laboratory models or in humans related to surgery and cancer; (2) laboratory and clinical studies that examine the biochemical, cytokinetic, immunological, and nutritional effects of cancer surgery; (3) therapeutic studies in which surgery or a surgical question is the primary treatment modality; (4) novel immunotherapy procedures such as assessment of specific lymphokines stimulated cells and autologous vaccines which require surgical input; (5) new surgical techniques relevant to staging or care of patients; (6) studies to identify prognostic factors relevant to the treatment of cancer patients; (7) surgical supportive care; (8) regional chemotherapy or hyperthermia or radiation in which a surgical approach to the treatment site is a major aspect of the procedure. This PA is not restricted to the areas of surgical oncology research listed above.

Objectives

The aims of this initiative are two-fold: (1) to promote academic research in surgical oncology and (2) to stimulate development of innovative surgical related clinical studies with laboratory correlations so as to foster the development of interactions between basic science laboratories and clinicians performing these clinical trials.

STUDY POPULATION

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in the Research Plan, 1-4 AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the receipt dates as indicated in the application kit (February 1, June 1, and October 1). Specific application procedures for interactive R01 applications can be found in the NIH Guide for Grants and Contracts (Vol. 21, No. 1, January 10, 1992) under PA-92-29.

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301-496-7441. The title and number of the announcement must be typed in item 2a on the face page of the application.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources are requested to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator must be included with the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the customary NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Roy S. Wu
Program Director, Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

Direct inquiries regarding fiscal matters to:

Ms. Carolyn Mason
Grants Management Specialist
National Cancer Institute
Executive Plaza South, Room 242
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 59
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.395, Cancer Treatment Research. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SJOGREN'S SYNDROME AND SALIVARY DYSFUNCTION

NIH GUIDE, Volume 21, Number 20, May 29, 1992

PA: PA-92-82

P.T. 34; K.W. 0715148, 1002034, 0755030, 0785055, 0745020, 0765033

National Institute of Dental Research

PURPOSE

Sjogren's syndrome is one of the major causes of xerostomia, the most common manifestation of salivary gland dysfunction. The National Institute of Dental Research (NIDR) supports studies to improve knowledge of the development, structure, function, and diseases of the salivary glands and to determine the influence of salivary constituents on oral health. Toward this end, the NIDR seeks to stimulate basic and clinical research, research training, and manpower development in the broad area of the epidemiology, etiology, pathogenesis, diagnosis, and treatment of xerostomia, particularly in relation to Sjogren's syndrome.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement (PA), Sjogren's Syndrome and Salivary Dysfunction, is related to the priority area of oral health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Domestic applications may include international components. Applications from minority individuals and women are encouraged. Special eligibility requirements specified in the pertinent guidelines for the various mechanisms available for support of this program must be met. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) Award.

MECHANISMS OF SUPPORT

The mechanisms available for support of this program include the traditional Research Project Grant (R01), the Program Project Grant (P01), the FIRST Award (R29), the small grant (R03), the Postdoctoral Individual Fellowship (F32), and Senior Fellowship (F33) Awards, and the following career development awards: the Modified Research Career Development Award (K04), the Physician Scientist for Dentist Award (K11), and the Individual Dentist Scientist Award (K15).

RESEARCH OBJECTIVES

Background

The importance of saliva in oral health has become increasingly apparent in the expanding aged population. Here, advances in medical procedures and utilization of medication have been combined in an effort to maintain the "quality of life." However, a common sequela to this effort is an increased prevalence of salivary dysfunctions. The most common clinical manifestation of salivary dysfunction is a decreased output of secretion, termed "dry mouth" (hyposalivation, xerostomia, or asialorrhea). Clinically, dry mouth may vary from a slight reduction in salivary flow with transitory inconvenience to a total xerostomia with severe difficulties in speech, mastication, swallowing, digestion, and concomitant physical and psychological indisposition. The major causes of xerostomia include local and systemic disease, pharmacological agents, radiation therapy, immunological disorders, menopause, and environmental pollution. Hyposalivation may lead to qualitative and/or quantitative changes in the protective salivary films or pellicles that coat hard and soft tissues. This loss of an enamel or cemental pellicle could result in an increase in plaque-mediated diseases, namely, dental caries and gingivitis, that ultimately result in tooth loss. Alteration in mucosal pellicle may make the oral soft tissues more susceptible to desiccation and environmental insult, leading to colonization by an opportunistic microflora. The end result may be painful ulcerations and/or local infections with a very sensitive mucous membrane, with consequent difficulties in accepting dental prostheses.

There are, apparently, no available prevalence or incidence data to describe the frequency of Sjogren's syndrome in any population. It has been estimated that in the United States there are, at minimum, two million such patients--the vast majority being postmenopausal women. Another two million undiagnosed victims are estimated to suffer with the disease. Some cases may develop during childhood. About half of the cases are primary; the remainder are secondary. Similarly, there are no accurate data describing the frequency of iatrogenic salivary dysfunctions, especially those related to specific pharmaceutical use. It has been suggested that over 400 drugs in the Physician's Desk Reference result in salivary gland dysfunction. This claim, however, is often based on subjective and anecdotal information and not objective evaluations of gland performance. Specifically, detailed epidemiologic data are required for the prevalence and incidence of Sjogren's Syndrome and for various iatrogenic disorders.

The etiology and pathogenesis of Sjogren's syndrome are not clearly understood. Sjogren's syndrome is a chronic, multisystem, autoimmune disorder. The lesion in this disease is an immunologically mediated inflammatory exocrinopathy that starts with periductal infiltration of the salivary tissue by plasma cells and lymphocytes. The glandular acini atrophy and progressively disappear, being replaced by a dense infiltrate of lymphocytes. Sjogren's syndrome may be caused by T-cell abnormalities or a deficiency of T lymphocytes and subsequent overactivity of other lymphocytes and the production of autoantibodies. Specific antinuclear antibodies, the SS-A (Ro) and SS-B (La) antibodies, are found in Sjogren's syndrome and may have diagnostic value in patients with unexplained parotid swelling or other features such as renal and pulmonary lesions. These antibodies may antedate clinical evidence of Sjogren's syndrome by months or years. Salivary duct autoantibodies are another characteristic finding in this disease, but it appears that these antibodies may be causally unrelated to the duct damage. Whether the apparent disturbance in immunoregulation in Sjogren's syndrome is due to predominantly environmental or genetic factors is unknown. In addition to the existence of genetic predisposition to Sjogren's syndrome, it appears that the two variants (i.e., primary and secondary) of this disorder, though related, have distinct differences in genetics. Although the Epstein-Barr virus has received, over the past decade, continued attention as one virus that might possibly play a role in Sjogren's syndrome, a causal relationship has not been proven. It was recently reported that a newly discovered human retrovirus (the human intracisternal A-type retroviral particle) might be involved in Sjogren's syndrome and perhaps in a variety of other autoimmune diseases. The finding of this virus in relation to Sjogren's syndrome is important and needs to be confirmed. Many investigators feel that estrogen may also be a factor since 90 percent of those with this disease are women.

There is a real need for rigorous clinical trials to test the efficacy and safety of various treatment regimens designed to correct or improve specific salivary dysfunctions. These include trials to improve secretory capabilities of patients who retain functional gland parenchyma (responder patients). Pilocarpine is one parasympathomimetic drug that has been extensively and rigorously tested and that has been shown to be useful for many patients. Other pharmaceuticals that have been suggested to benefit responder patients include bromhexine (bisolvin) and anethole-trithione (sialor). Clinically, artificial salivas have served as a replacement modality for individuals exhibiting hyposalivation and those lacking functional glands (nonresponder patients). For sale as an "over-the-counter" item, artificial salivas have been traditionally formulated to replenish particular functions of saliva such as lubrication, viscosity, tissue hydration, surface tension, and/or antimicrobial properties. Currently available products appear to be less than ideal, since their effects are of limited duration, and they may either have an unpleasant taste or irritate the mucosa. Since a clearly promising saliva substitute does not yet exist, proposed studies would very likely be of the pilot or screening type. Additionally, it has been suggested that active stimulation of salivary secretion during head and neck radiation may reduce the iatrogenic salivary hypofunction associated with this therapeutic procedure. It would be useful to test the utility of a proven, effective sialogogue, like pilocarpine, for such preventive therapy.

Research Goals and Scope

Based on recommendations by the Dental Research Programs Advisory Committee at its June 7-8, 1988 and April 7-8, 1992 meetings, the NIDR "Broadening the Scope: Long-Range Research Plan for the Nineties," and the NIDR/Fogarty

International Center Report on "International Collaboration for Oral Health Research" (Philip J. Holloway, April 1989), applications are invited for research project grants (including minority research supplements), program project grants, FIRST awards, small grants, career development awards, and postdoctoral fellowships in the broad area of the epidemiology, etiology, pathogenesis, diagnosis, and treatment of xerostomia, particularly in relation to Sjogren's syndrome. Some examples of research areas of interest include, but are not limited to:

- o Development of reliable epidemiological data on the prevalence and incidence of salivary gland disorders, such as Sjogren's syndrome and xerostomia related to systemic medications, particularly among target populations such as the aged and others at high risk.
- o Further investigations on the etiology and pathogenesis of diseases and conditions that cause xerostomia. This research should include development of sophisticated model systems (cell culture and transgenic animals) to investigate normal cellular processes and those evident in disease.
- o Development of improved methods, including more sensitive and specific assays using saliva, to diagnose specific salivary gland disorders.
- o Development and improvement of treatments for salivary hypofunction, including genetic manipulation and development of organoids.
- o Development of new sialogogues and improved, long-acting saliva substitutes.
- o Development of methods to expand and improve function of residual salivary gland tissue after destructive disease or therapy (e.g., radiation and chemotherapy to treat head and neck cancers). This research should include methods aimed at tissue repair and regeneration.
- o Development of techniques for the preservation and transplantation of salivary glands.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in items 1-4 of the Research Plan AND summarized in item 5, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans [including American Indians or Alaskan Natives], Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications will be accepted on an indefinite basis in accordance with the receipt, Initial Review Group, National Advisory Council and earliest possible beginning dates specified in the pertinent application kits.

The specific application forms and kits required in this connection are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441. The application form PHS 398 must be used for research projects (R01, R29, P01, and R03) and the Career Development Awards (K07, K11, and K15). The application form PHS 416-1 must be used for fellowships (F32 and F33). The YES box must be checked and the title and number of the announcement must be typed in item 2a on the face page of the application form PHS 398 (rev. 9/91). In the case of fellowship applications, the announcement title must be typed in item 3 on the face page of form PHS 416-1 (rev. 7/88).

The completed original application form PHS 398 and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

When using the PHS 416-1 fellowship application, submit the original and two copies to the above address.

REVIEW PROCEDURES

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of either the Division of Research Grants, NIH or the NIDR, in accordance with the standard NIH peer review procedures and the review criteria customary for the support mechanism selected. Following scientific-technical review, the applications will receive a second-level review by an appropriate national advisory council or board.

AWARD CRITERIA

Applications recommended for further consideration will compete for available funds with all other applications. The following will be considered in making funding decisions:

- o quality of the proposed project as determined by peer review
- o availability of funds
- o program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

G.G. Roussos, Ph.D.
Director, Salivary Research and Oral Biology Centers Program
Extramural Program
National Institute of Dental Research
Westwood Building, Room 505
Bethesda, MD 20892
Telephone: (301) 496-7884

Direct inquiries regarding fiscal matters to:

Ms. Theresa Ringler
Chief, Grants Management Office
Extramural Program
National Institute of Dental Research
Westwood Building, Room 518
Bethesda, MD 20892
Telephone: (301) 496-7437

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.121. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-77788-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

5333 Westbard Avenue
Bethesda, MD 20816

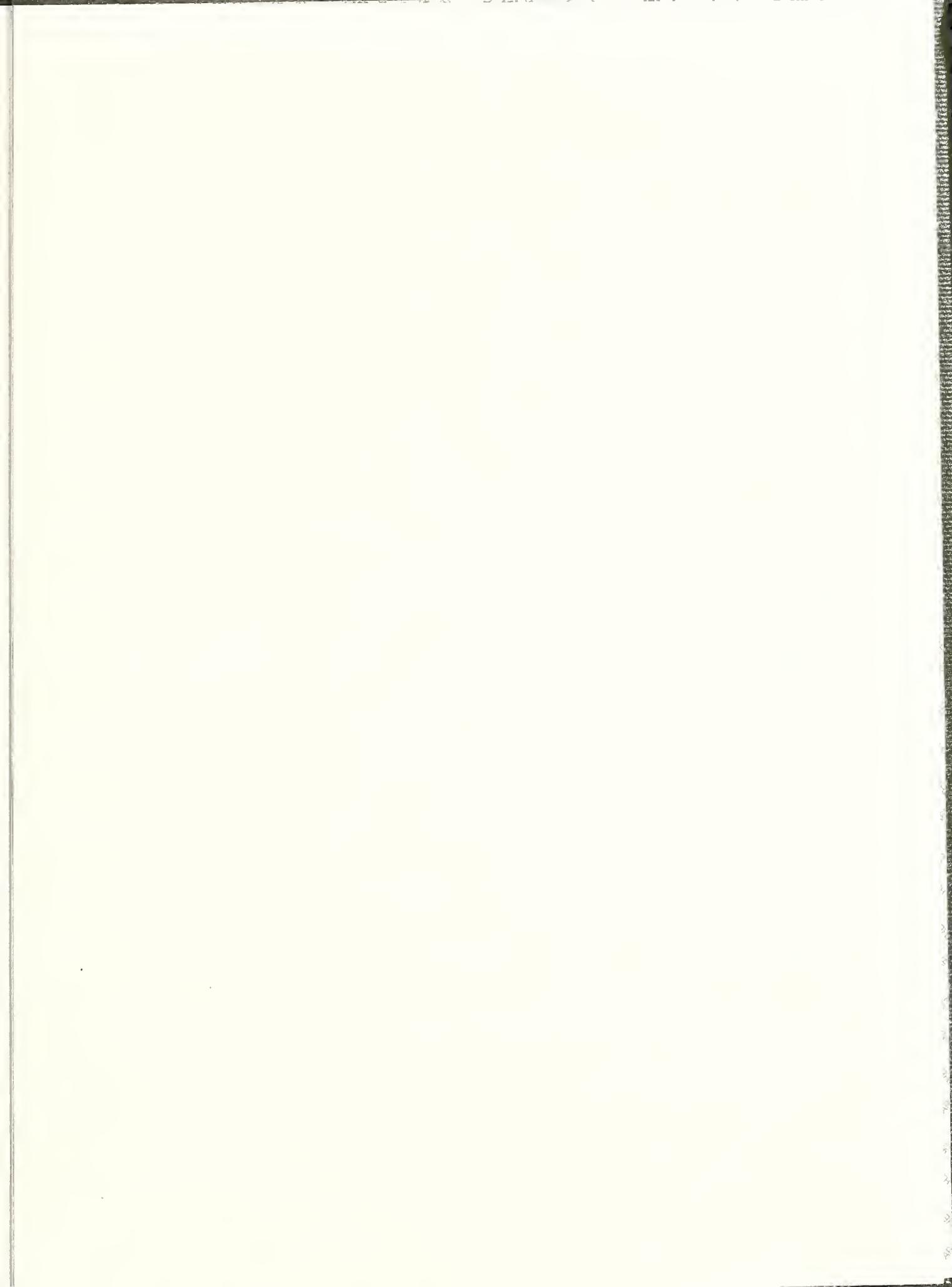


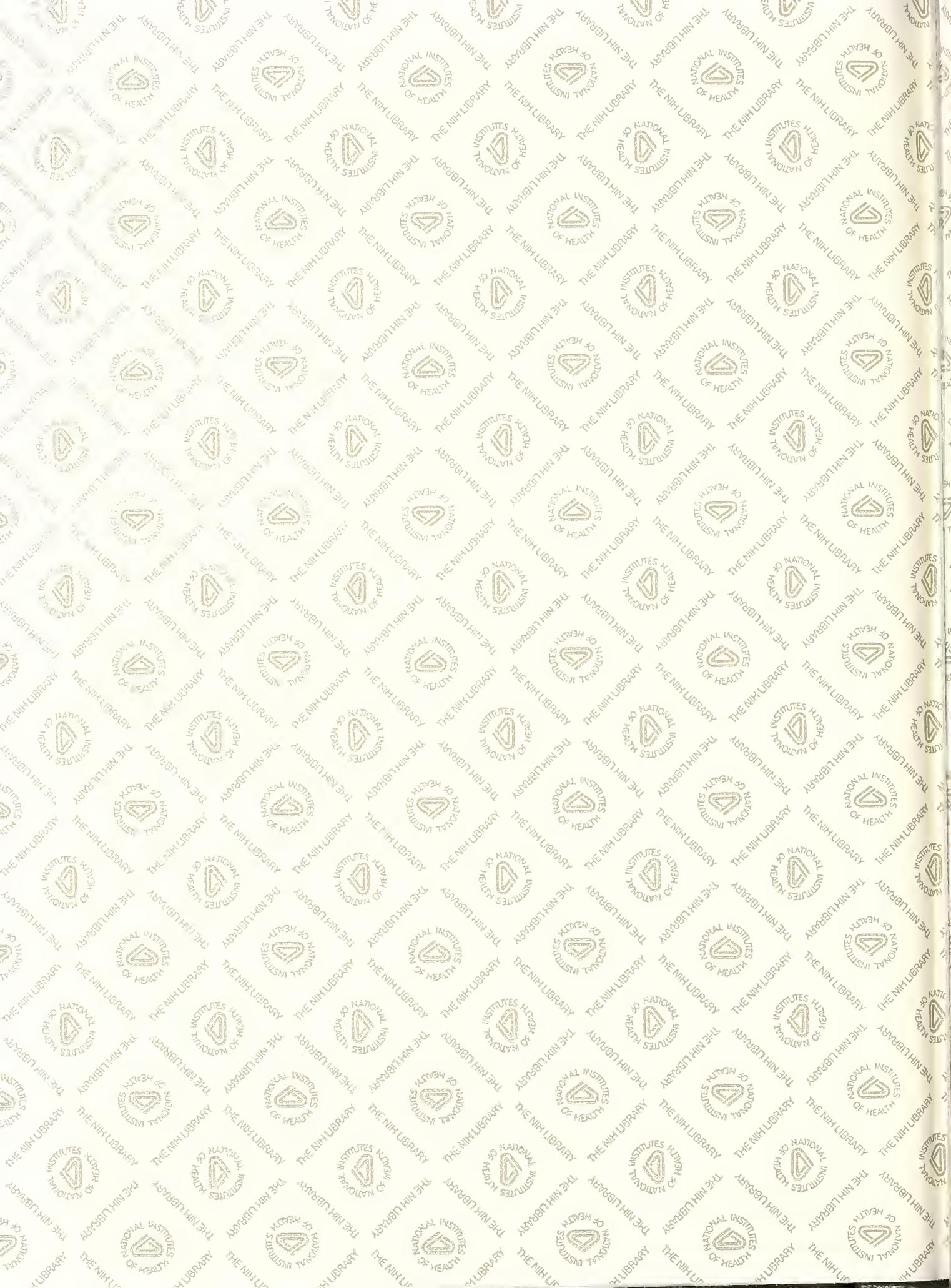


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